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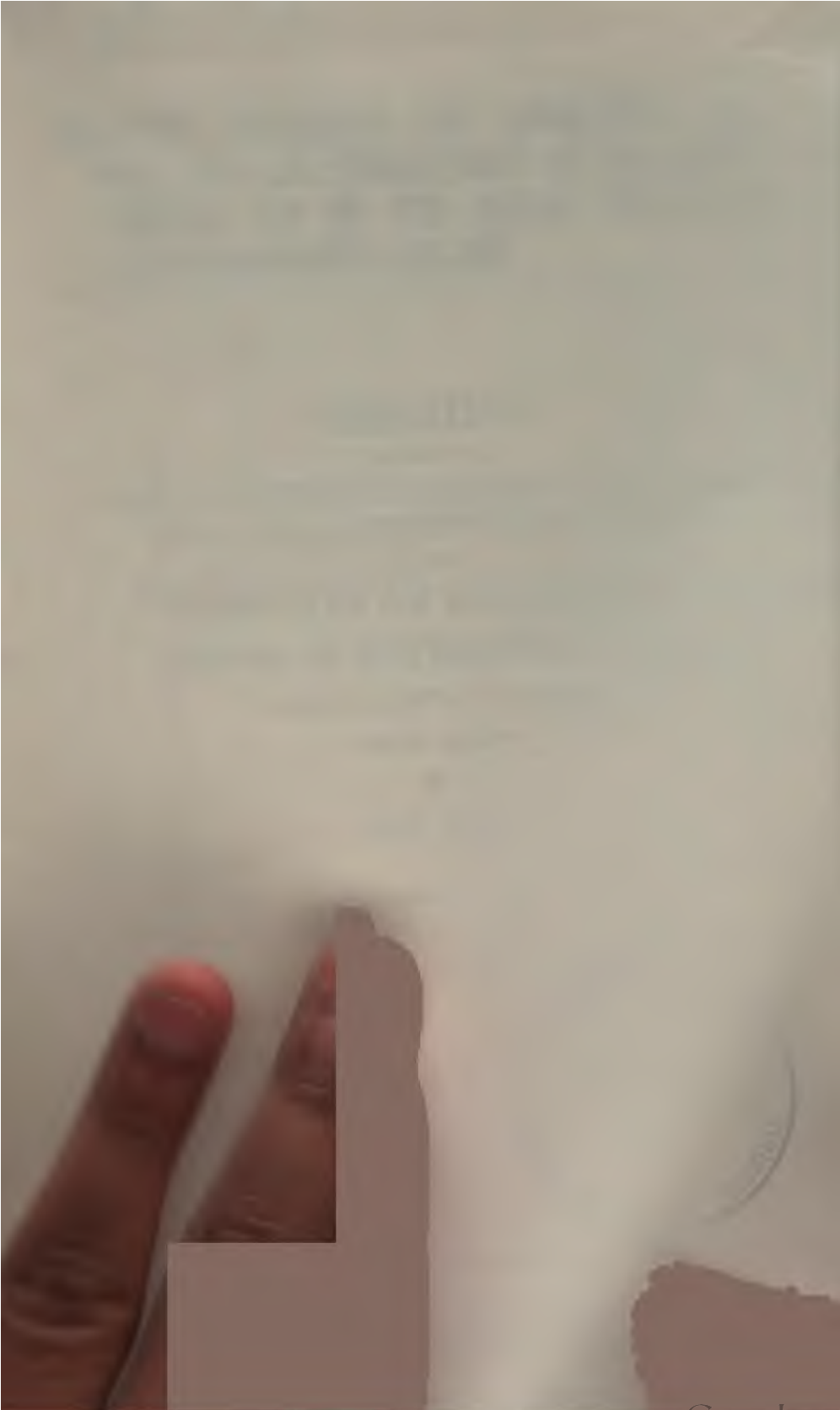
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**IMPROVED STANDARDS FOR LABORATORY ANI-
MALS ACT; AND ENFORCEMENT OF THE ANIMAL
WELFARE ACT BY THE ANIMAL AND PLANT
HEALTH INSPECTION SERVICE**

HEARING

BEFORE THE

**SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE**

OF THE

**COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES**

NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

H.R. 5725

SEPTEMBER 19, 1984

Serial No. 98-86

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IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT; AND ENFORCEMENT OF THE ANIMAL WELFARE ACT BY THE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

WEDNESDAY, SEPTEMBER 19, 1984

**HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
*Washington, DC.***

The subcommittee met, pursuant to notice, at 10 a.m., in room 1302, Longworth House Office Building, Hon. George E. Brown, Jr. (chairman of the subcommittee) presiding.

Present: Representatives Staggers, Penny, Foley, Volkmer, Roberts, Gunderson, Evans of Iowa, and Franklin.

Also present: Representative Rose, a member of the full committee.

Staff present: Cristobal P. Aldrete, special counsel; Glenda L. Temple and Peggy L. Pecore, clerks; William A. Stiles, Jr., Jim Davis, and Gerald R. Jorgensen.

OPENING STATEMENT OF HON. GEORGE E. BROWN, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. BROWN. The subcommittee will come to order.

I would like to thank all of those who have come today to discuss the enforcement of the Animal Welfare Act in regard to laboratory animals and the legislation which we have introduced, H.R. 5725, the Improved Standards for Laboratory Animals Act of 1984.

This bill would amend the Animal Welfare Act to help ensure a more humane and uniform approach to the treatment of laboratory animals. It is a revised version of S. 657, introduced by our distinguished colleague in the Senate, Senator Dole.

The use of live animals in research is not a new issue for me nor for the Congress. Both those concerned with animal care and those involved in the science community have come a long way in their perspective on this issue. While several legislative remedies have been introduced, I feel that H.R. 5725, which has over 50 cosponsors, offers a reasonable and effective approach to the problem.

Today we will receive testimony from the Animal and Plant Health Inspection Service and from the National Institutes of Health, as well as from a cross-section of science, agriculture, and

animal care organizations. I have already received several carefully thought-out suggestions regarding H.R. 5725.

It is my hope that today we will continue our education about the issues at hand and enter into constructive discussion on methods to better ensure the humane treatment of laboratory animals. We will explore the question of whether animals are receiving adequate care in existing facilities.

During recent years, there has been an increasing concern among the public that some laboratories are below currently set standards. H.R. 5725 would address this problem by initiating a form of self-regulation by each facility using live animals by means of animal research committees.

Also in question today is whether current law adequately addresses the humane care of laboratory animals. At present, there is no law which requires researchers to use painkillers during an experiment causing pain to animals. My legislation would require this as well as other strengthening measures, unless they would specifically interfere with the research protocol.

Because more than one Federal agency undertakes research using live animals, and several independent facilities use animals, there is concern that there is unnecessary duplication of experiments. The legislation before us would provide for a voluntary national data base which would help reduce unintended duplication and ensure that researchers are aware of their alternatives.

I have received numerous comments regarding H.R. 5725 since its introduction in May 1984, including hundreds of supportive letters and signed petitions, some signed by doctors, nurses, and other professionals in the medical field. However, it is clear that there is real concern that legislation could lead to an interference with scientific freedom, or create a large regulatory or financial burden on their facilities.

H.R. 5725 would not interfere with the freedom of the decision of a scientist to conduct an experiment but instead takes precautions to ensure that humane handling of the animals occurs whenever possible.

I have often been asked why I made the decision to introduce this legislation. I have been one of the more active advocates and supporters of science in this House. However, I feel that we cannot allow any field, whether it be defense, science, or any others, to be free from scrutiny or improvement. I feel strongly that while medical research is vital to the health of our society, we must accept the responsibility which comes with using live animals. We should ensure that needless suffering is eliminated.

As all of you are aware, we have a long day ahead of us. Because of the strong interest in this hearing, I felt that we should allow as many people as possible to comment on the topics at hand. We have put spokesmen with differing viewpoints on the same panel. I hope that this will encourage constructive discussion.

However, this will require that we exercise certain discipline with regard to the use of time, and I am going to ask the witnesses to hold their testimony down to 5 minutes, with, of course, the opportunity to include any additional material that they wish in the record, and it will be made a part of the record.

I would also like to ask that all the witnesses confine themselves as much as possible to the topic of this hearing, as time is at a premium. I am looking forward to all of your comments.

[H.R. 5725 and the report from U.S. Department of Agriculture follow:]

98TH CONGRESS
2D SESSION

H. R. 5725

To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals.

IN THE HOUSE OF REPRESENTATIVES

MAY 24, 1984

Mr. BROWN of California (for himself and Mr. FOLEY) introduced the following bill; which was referred to the Committee on Agriculture

A BILL

To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SHORT TITLE

4 SECTION 1. This Act may be cited as the "Improved
5 Standards for Laboratory Animals Act".

6 FINDINGS

7 SEC. 2. The Congress finds that—

8 (1) methods of testing that do not use animals
9 have been developed which show promise of being
10 faster, less expensive, and more accurate than tradi-
11 tional animal experiments for some purposes and fur-

3 (2) measures which eliminate or minimize the un-
4 necessary duplication of experiments on animals can
5 result in more productive use of Federal funds; and

9 DEFINITIONS

(b)(1) Subsections (f), (g), (h), (i), and (j) of section 2 of such Act are redesignated as subsections (i), (j), (k), (l), and (m), respectively.

20 “(f) The term ‘Federal agency’ means an executive
21 agency as such term is defined in section 105 of title 5,
22 United States Code, and with respect to any research facility
23 means the agency from which the research facility has re-
24 ceived or may receive a Federal award for the conduct of
25 research, experimentation, or testing, involving the use of
26 animals;

1 “(g) The term ‘Federal award for the conduct of re-
2 search, experimentation, or testing, involving the use of ani-
3 mals’ means any mechanism (grant, award, loan, contract, or
4 cooperative agreement) under which Federal funds are pro-
5 vided to support the conduct of such research;

6 “(h) The term ‘quorum’ means a majority of the com-
7 mittee members;”.

8 (c) For purposes of this Act, the term “animal” shall
9 have the same meaning as defined in section 2(j) of the
10 Animal Welfare Act (7 U.S.C. 2132(j)), as redesignated by
11 subsection (b)(1).

12 STANDARDS AND CERTIFICATION PROCESS

13 SEC. 4. (a) Subsection (a) of section 13 of the Animal
14 Welfare Act (7 U.S.C. 2143(a)) is amended by inserting
15 “(1)” after “(a)”.

16 (b) The second sentence of such subsection is amended
17 to read as follows: “Such standards shall include—

18 “(A) requirements with respect to handling, hous-
19 ing, feeding, watering, sanitation, ventilation, shelter
20 from extremes of weather and temperatures, and ade-
21 quate veterinary care, including the appropriate use of
22 anesthetic, analgesic, or tranquilizing drugs, when such
23 use would be proper in the opinion of the attending
24 veterinarian of such research facilities;

1 “(B) provisions for separation by species where
2 the Secretary finds that such separation is necessary
3 for humane handling;

4 “(C) exercise for dogs, and
5 exceptions to such standards may be made only when speci-
6 fied by research protocol.”.

7 (c) The last sentence of such subsection is amended to
8 read as follows: “Nothing in this Act shall be construed as
9 authorizing the Secretary to promulgate rules, regulations, or
10 orders with regard to design, outlines, or guidelines of actual
11 research or experimentation by a research facility. The Sec-
12 retary shall promulgate standards for research facilities, in-
13 cluding requirements for animal care, treatment, and prac-
14 tices in experimental procedures to ensure that animal pain
15 and distress are minimized. The Secretary shall require every
16 research facility to be able to show that the professionally
17 acceptable standards governing the care, treatment, and
18 practices on animals, including appropriate use of anesthetic,
19 analgesic, and tranquilizing drugs during experimentation,
20 are being followed by the research facility during research
21 and experimentation. The Secretary shall require, at least
22 annually, every research facility to report that the standards
23 governing the care, treatment, and practices on animals are
24 being followed. In its statement of compliance, the research

1 facility shall provide assurances satisfactory to the
2 Secretary—

3 “(A) demonstrating that the principal investigator
4 has considered alternatives to any procedure likely to
5 produce pain to or distress in an experimental animal
6 and shall provide details of any procedure likely to
7 produce pain or distress in any experimental animal;
8 and

9 “(B) in any practice involving pain to unanesthe-
10 tized animals—

11 “(i) that a doctor of veterinary medicine has
12 been consulted in the planning of such procedures;

13 “(ii) for the use of tranquilizers, analgesics,
14 and anesthetics;

15 “(iii) for pre- and post-surgical care by labo-
16 ratory workers in accordance with established
17 medical and nursing procedures;

18 “(iv) against the use of paralytics without
19 anesthesia; and

20 “(v) that the withholding of tranquilizers, an-
21 esthesia, analgesia, or euthanasia when scientifi-
22 cally necessary shall continue for only the neces-
23 sary period of time; and

24 “(C) except in cases of scientific necessity or
25 other special circumstances as determined by the

1 animal research committee, assurances that no animal
2 may be used in more than one major operative proce-
3 dure from which it is allowed to recover.

4 “(2) Paragraph (1) shall not prohibit any State (or a
5 political subdivision of such State) from promulgating stand-
6 ards in addition to those standards promulgated by the Secre-
7 tary under paragraph (1).”.

8 (d) Subsection (a) of such section is amended by adding
9 at the end thereof the following:

10 “(3)(A) The Secretary shall require that each research
11 facility establish an animal research committee (hereinafter in
12 this subsection referred to as the ‘committee’). Each animal
13 research committee shall be appointed by the chief executive
14 officer of such research facility and shall be composed of not
15 fewer than three members. Such members shall possess suffi-
16 cient ability to assess animal care, treatment, and practices in
17 experimental research as determined by the needs of the re-
18 search facility. Of the members of the committee—

19 “(i) at least one member shall be a doctor of vet-
20 erinary medicine;

21 “(ii) at least one member shall have no association
22 with such facility and shall be responsible for repre-
23 senting community concerns regarding the welfare of
24 animal subjects; and

1 “(iii) in those cases where the committee consists
2 of more than three members, not more than three
3 members shall be from the same administrative unit of
4 such facility.

5 “(B) A quorum shall be required for all formal actions of
6 the committee, including—

7 “(i) inspecting at least semiannually all animal
8 study areas and facilities of such research facility;

9 “(ii) reviewing as part of the inspection of such
10 research facility practices involving pain to unanesthe-
11 tized animals and the condition of research animals to
12 ensure compliance with the standards of animal care,
13 treatment, and practices and that pain and distress to
14 such animals is minimized.

15 “(C)(i) The committee shall file each inspection certifica-
16 tion report at the research facility. Such report shall—

17 “(I) be signed by a majority of the committee
18 members involved in the inspection;

19 “(II) include reports of any violation of the stand-
20 ards promulgated by the Secretary, including any defi-
21 cient conditions of animal care or treatment and any
22 deviations of research practices from originally ap-
23 proved proposals that adversely affect animal welfare;

24 “(III) include any minority views of the commit-
25 tee; and

1 “(IV) include any other information pertinent to
2 the activities of the committee.

3 “(ii) Such report shall be maintained for at least three
4 years by the research facility and shall be available for in-
5 spection by the Secretary or the funding Federal agency.

6 “(iii) In order to give the research facility an opportuni-
7 ty to correct any deficiencies or deviations discovered by
8 reason of subparagraph (B), such committee shall notify the
9 administrative representative of the research facility of any
10 unacceptable conditions. If, after notification and an opportu-
11 nity to make corrections, such conditions remain unaccept-
12 able, the committee shall notify the Animal and Plant Health
13 Inspection Service of the Department of Agriculture and the
14 funding Federal agency, in writing, of such conditions.

15 “(D) The inspection results shall be available to Depart-
16 ment of Agriculture inspectors for review during inspections.
17 Department of Agriculture inspectors shall forward any com-
18 mittee inspection records which include reports of deficiencies
19 or deviations to the Animal and Plant Health Inspection
20 Service of the Department of Agriculture and any funding
21 Federal agency.

22 “(4) The research facility shall provide for annual ses-
23 sions for scientists, animal technicians, and other personnel
24 involved with animal care and treatment in such facility.
25 Such sessions shall provide instruction or training in—

1 “(A) the humane practice of animal maintenance
2 and experimentation;

3 “(B) research or testing methods that minimize or
4 eliminate the use of animals or limit animal pain or dis-
5 tress; and

6 “(C) utilization of the information service at the
7 National Agricultural Library, established under sub-
8 section (e), to prevent unintended or unnecessary dupli-
9 cation of animal experimentation as determined by the
10 needs of the research facility.

11 “(5) Research facilities shall inform their employees of
12 the provisions of this section and shall inform such employees
13 to report to the committee any violations of such provisions.
14 Employees of such facilities may not be discriminated against
15 on grounds that such employees reported any violation of
16 such provisions.”.

17 (e) Section 13 of the Animal Welfare Act (7 U.S.C.
18 2143) is amended by adding at the end thereof the following:

19 “(e) The Secretary shall establish an information service
20 at the National Agricultural Library. Such service shall, in
21 cooperation with the National Library of Medicine, provide
22 information on improved methods of animal experimentation
23 including methods which could—

24 “(1) reduce or replace animal use;

1 “(2) minimize pain and distress to animals, such
2 as anesthetic and analgesic procedures; and

3 “(3) prevent unintended duplication between re-
4 search facilities of animal experimentation as deter-
5 mined by the needs of the research facility.

6 “(f) In any case in which the funding Federal agency
7 determines that conditions of animal care, treatment, or prac-
8 tice in a particular project have not been in compliance with
9 applicable standards, despite notification to the research facil-
10 ity, that agency shall suspend or revoke Federal support for
11 the project. Any research facility losing Federal support as a
12 result of actions taken under the preceding sentence shall
13 have the right of appeal as provided in sections 701 through
14 706 of title 5, United States Code.”.

15 SEC. 5. Section 21 of the Animal Welfare Act (7 U.S.C.
16 2151) is amended by inserting before the period “, except
17 that no rule, regulation, or order may require a research fa-
18 cility to disclose trade secrets or commercial or financial in-
19 formation which is privileged or confidential”.

20 SEC. 6. The Animal Welfare Act (7 U.S.C. 2131-2156)
21 is amended by adding at the end thereof the following
22 section:

23 “SEC. 27. (a) It shall be unlawful for any member of the
24 animal research committee to release any confidential infor-
25 mation of the research facility, including any information that

1 concerns or relates to the trade secrets, processes, oper-
2 ations, style or work, or apparatus, or to the identity, confi-
3 dential statistical data, amount or source of any income, prof-
4 its, losses, or expenditures of the research facility.

5 “(b) It shall be unlawful for any member of such com-
6 mittee to use or attempt to use to his advantage, or reveal to
7 any other person, any information which is entitled to protec-
8 tion as confidential information under subsection (a).

9 “(c) A violation of subsection (a) or (b) is punishable
10 by—

11 “(1) removal from such committee, and

12 “(2)(A) a fine of not more than \$1,000 and im-
13 prisonment of not more than 1 year, or

14 “(B) if such violation is willful, a fine of not more
15 than \$10,000 and imprisonment of not more than 3
16 years.

17 “(d) Any person, including any research facility, injured
18 in its business or property by reason of a violation of this
19 section may recover all actual and consequential damages
20 sustained by such person and the cost of the suit including
21 reasonable attorney’s fees. Nothing in this section shall be
22 construed to affect any other rights that any such person may
23 have, nor shall this paragraph be construed to limit the exer-
24 cise of any such rights arising out of or relating to a violation
25 of subsections (a) and (b).”.

1 **EFFECTIVE DATE**

2 **SEC. 7. This Act shall take effect beginning one year**
3 **after the date of enactment of this Act.**

○



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

October 3 1984

Honorable E (Kika) de la Garza
Chairman, Committee on Agriculture
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This is in response to your request for the Department of Agriculture's recommendations on H.R. 5725, a bill "To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals."

The bill, H.R. 5725, is similar to and has the same purpose as S. 657, i.e., to ensure the proper treatment of laboratory animals. On October 12, 1983, this Department submitted a report on S. 657 to the Senate Committee on Agriculture, Nutrition, and Forestry. While H.R. 5725 addresses some of our objections to S. 657, we continue to believe that our common goals of ensuring proper care and treatment and appropriate use of laboratory animals can be achieved under current authorities. Therefore, we do not recommend enactment of H.R. 5725. However, we wish to be on record as strongly supporting humane care and treatment of animals used for purposes of biomedical research.

Our comments on the bill, H.R. 5725, are enclosed.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,


John R. Block
Secretary

Enclosure

Comments of the
Department of Agriculture
on H.R. 5725

The bill amends the Animal Welfare Act as follows:

1. Expands the definition of the term "research facility" to include each department, agency or instrumentality of the United States which uses animals for research or experimentation; defines the term "Federal agency" to mean any Executive agency from which a research facility has received or may receive Federal funds to support the conduct of research, experimentation or testing involving the use of animals; and, makes it clear that the definition of "animal" is the same as that provided under the current Act.

2. Deletes the language stating that minimum requirements be applied to the standards promulgated by the Secretary of Agriculture to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities and exhibitors; adds exercise for dogs as a standard; and, allows the Secretary to make exceptions to the standards, but only when such exceptions are specified by the research protocol.

3. Requires the Secretary to promulgate standards for research facilities, including requirements for animal care, treatment, and practices in experimental procedures, to ensure that animal pain and distress are minimized. Requires each research facility, in its annual statement of compliance, to provide the Secretary of Agriculture with assurances that such standards are being followed. Also requires the research facility to provide annual training sessions for personnel involved with animal care and treatment.

4.. Provides that any State (or political subdivision of that State) may promulgate standards in addition to those promulgated by the Secretary.

5. Mandates the establishment and makeup of an animal research committee of three or more members within each research facility. Makes it unlawful for, any member of the committee to release trade secrets or confidential information. The committee must make inspections at least semiannually of all animal study areas of the research facility and file an inspection report which must remain on file at the research facility for three years. The committee must notify, in writing, the Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture and the funding Federal agency of any unacceptable conditions that are not corrected despite notification. Federal support for a particular project can be suspended or revoked for continued failure by a research facility to comply with the standards of animal care, treatment or practices such suspension or revocation may be appealed.

6. The inspection results of the animal research committee must be available to the Department of Agriculture's inspectors for review during inspection. These inspectors must forward to APHIS and the funding Federal agency any inspection records of the committee which include reports of any deficient conditions of animal care or treatment and any deviations of research practices from the originally approved proposal that adversely affect animal welfare.

7. Prohibits the Secretary from promulgating rules, regulations, or orders that may require a research facility to disclose trade secrets or commercial or financial information which is privileged or confidential.

8. Mandates the establishment of an information service on improved methods of animal experimentation at the National Agricultural Library.

The Department of Agriculture, through APHIS, administers the Animal Welfare Act. APHIS is required to register State-owned and privately-owned research facilities and inspect their research sites to ensure compliance with the Department of Agriculture's standards of animal care and treatment. Currently, there are 1,166 registered facilities with approximately 3,300 research sites. Federal agencies are not required to register with APHIS, and their laboratories are not inspected by APHIS. Federal agencies are responsible for ensuring that their laboratories comply with the Department of Agriculture standards. However, both APHIS registered research facilities and Federal laboratories must submit an annual compliance report to APHIS stating whether any regulated animals were used for research, testing, teaching, or experimentation, any procedures involved were painful, and, when pain-relieving drugs were omitted during any painful procedures. Therefore, we question the need to expand the definition of "research facility" to include Federal laboratories, making these laboratories subject to APHIS registration and inspection.

Deletion of the term "minimum" as the lower limit for standards of animal care and treatment would require the development of new regulations. Such an approach would make it very difficult to reach an agreement on a final set of standards.

We do not favor adding "exercise for dogs" as a required standard. Our regulations require that the primary enclosure for each animal, including dogs, be constructed and maintained to allow the animal adequate space for freedom of movement in all directions. Our inspectors pay special attention to animals kept in small enclosures to ensure that the space provided meets our requirements, unless restricted space is specified by the research protocol.

Under our current registration procedures each research facility and the responsible attending veterinarian must agree to a program of adequate veterinary care. A copy of the agreement is retained by the participants, including the Department of Agriculture inspector, and a copy is sent to the Area Veterinarian in Charge (AVIC) of the State where the facility is located.

When compliance inspections are conducted, our inspectors must document any deficient conditions of animal care and treatment and together with the attending veterinarian review the research protocols for any deviations from the established veterinary care program. The funding Federal agency is notified of any major deficient conditions, as well as the schedule for compliance. Thus, the directives in the bill concerning the dissemination of information on deficient conditions and deviations from the protocol that would adversely affect animal welfare are being implemented administratively.

Currently, research facilities are required to keep records on the purchase, sale, transportation, identification and previous ownership of live dogs or

cats. They are also required to file reports regarding animal research, especially with respect to the use of pain-relieving drugs. The bill's prohibition against regulatory action that would require disclosure by a research facility of trade secrets or commercial or financial information which is privileged or confidential would make it difficult, if not impossible, to administer the recordkeeping provisions of the act. These provisions were enacted to assure humane treatment during research and to prevent the purchase, sale and use of stolen animals.

The establishment of an information system on improved methods of animal experimentation at the National Agricultural Library (NAL) can be achieved under current authorities. Presently, the NAL provides basic level services in support of programs within the Department. These services include collecting and indexing the leading publications in a particular field, document delivery, general reference, current awareness, and computerized bibliographies. Thus, with relatively little additional effort, NAL could expand these services to include animal experimentation.

Mr. BROWN. I now recognize Mr. Roberts, the ranking minority member, for any statement he may wish to make.

**OPENING STATEMENT OF HON. PAT ROBERTS, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS**

Mr. ROBERTS. Thank you, Mr. Chairman.

You have already indicated your long-time interest in scientific research and that you recognize the value of animal experimentation in furthering that research.

I would like to go a step further and thank you for your leadership in this whole area, and I look forward to working with you as well as my senior Senator from Kansas, Senator Bob Dole.

I think the fact is that we are holding a hearing that will demonstrate to all concerned that humane animal care is of concern, and that we cannot tolerate any substandard lab facilities or any inhumane animal treatment; that all who are engaged in animal research need to double their efforts to provide improved facilities and treatment.

We have many fine witnesses. It is their testimony that we have come to hear. With that, Mr. Chairman, I would simply ask that my full statement may be part of the record at this particular point.

Mr. BROWN. Without objection; it is so ordered.

[The prepared statement of Mr. Roberts follows:]

STATEMENT OF THE HONORABLE PAT ROBERTS

September 19, 1984

Mr. Chairman, I know of your long-time interest in scientific research and that you recognize the value of animal experimentation in furthering that research. You have indicated your belief that the legislation we have under consideration will not interfere with experiment procedures or results. However, I have several concerns.

The first deals with whether this legislation is absolutely necessary. It would appear to me that if laboratory standards are not being maintained then we should look to the United States Department of Agriculture for additional enforcement of the present Animal Welfare Act rather than giving additional legislative authority. I worry that the approach of H.R. 5725 is just added government regulation which will cost additional money, reduce the already limited funds for research, and in the long run will not contribute much to humane animal care. Does the Animal and Plant Health Inspection Service have the wherewithal to conduct the necessary surveillance or should additional funds and manpower be made available to them? I think we should explore all avenues to this problem before we pass added legislation which may or may not contribute to better animal care. The fact we are holding a hearing demonstrates to all involved that humane animal care is of concern and that we cannot tolerate substandard laboratory facilities or inhumane animal treatment and that all who are engaged in animal research need to double their efforts to provide improved facilities and treatment.

Mr. Chairman, I represent a district in Western Kansas that is heavily dependent upon animal agriculture. There is widespread concern over whether the proponents of this type of legislation wish to eliminate the use of animals in research and ultimately eliminate animal agriculture.

I would only say that millions of children through out the world are immunized against polio, diphtheria, mumps, measles, hepatitis and other diseases because of research done on animals. Every person who receives antibiotics or insulin for diabetes can thank animal experimentation. In short, Mr. Chairman we should never lose sight of the benefits that have come from animal research efforts.

And finally, in much of the mail my office has received on this legislation, the writer often alludes to the fact that many unnecessary tests are performed on animals and that these tests should be eliminated. However, Mr. Chairman, from the experience this subcommittee has had in dealing with FIFRA there seems to be another school of thought that we need more testing of chemicals and pesticides before registering them for use. There are those, within the animal welfare movement that say that substitute tests have been developed and these tests should be used instead of live animals. However, in testing for carcinogens there are no totally adequate substitutes for animal feeding studies. How we reconcile these differences is a task that will not be easy.

Having said this I want to assure you that with an open mind I look forward to assessing what the witnesses today have to say about this legislation. Thank you, Mr. Chairman.

Mr. BROWN. Does any other member care to comment at this point?

As is customary, we will first recognize Members of the Congress who have asked to testify. Senator Dole had asked to testify and expected to be here, and he may be here, but if he is not, we will insert his statement in the record. If he comes in later, we will, of course, recognize him to make that statement in person.

[The prepared statement of Senator Dole appears at the conclusion of the hearing.]

Mr. BROWN. The next Member of Congress is Hon. Charles Rose, a Member of Congress from North Carolina and a distinguished colleague on the Agriculture Committee.

Mr. Rose.

**STATEMENT OF HON. CHARLES ROSE, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF NORTH CAROLINA**

Mr. ROSE. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, I would like to thank you for the opportunity to testify before you today on H.R. 5725, a bill that amends the Animal Welfare Act to ensure the proper treatment of laboratory animals and which was introduced by you, Mr. Chairman, my colleague, and 49 of our colleagues in the Congress.

I feel that this is an extremely fair and realistic bill. This legislation establishes better requirements for the care and treatment of laboratory animals. It would assure that there are better standards for animal care and treatment.

Currently, the U.S. Department of Agriculture sends veterinarians to inspect these facilities. Although I believe that most of these laboratories are honest and professional in their care of these animals, I have seen, myself, Mr. Chairman, that there has been abuse. Either USDA inspectors are not thoroughly inspecting these facilities or there is not enough emphasis on the humane treatment of the animals involved.

This bill also authorizes that an animal welfare committee be established and that they meet twice annually to review the care of laboratory animals. This is important because, for the first time, the public and the people concerned with the treatment and well-being of animals will have input.

This legislation also establishes for the first time a data base that contains information on all of the completed animal research, something that, hopefully, would lead to an end to the much wasteful duplication that occurs in animal research. In addition, this data base will provide information on improved methods for minimizing pain and alternatives to using animals for research.

Mr. Chairman, I want to compliment you, as chairman of this subcommittee, for bringing this necessary and, unfortunately, controversial legislation to the attention of the committee. I am very distressed to learn that there are farm groups that are opposed to this legislation. Personally, I would hope that they could see that laboratory animals are not farm animals, and that because of the kinds of experiments that they undergo and the pain that they suffer, they deserve special attention.

In your statement, Mr. Chairman, you said that no frontier of science or of life in this country should be free from scrutiny and improvement. Scrutiny and improvement are exactly what I think is needed in this area. I am distressed that a great many of my friends in the agricultural sector do not believe that this is an important problem. They think that this can be laughed away or minimized.

I can assure them, as I am sure Senator Dole is aware and I am sure you are aware, Mr. Chairman, the American public is holding us to a higher standard of care in this area than has existed in the past.

I hope that my colleagues are not pressured into not studying this bill closely and giving it serious attention. The chairman has done a remarkable job, and he is giving all sides equal attention. I certainly hope that the little animals that do not have votes or voices will not be neglected, and I think this legislation moves to see that that does not take place.

Thank you, Mr. Chairman.

Mr. BROWN. Thank you very much, Mr. Rose.

I would now like to call on Mr. Bert Hawkins, the Administrator for the Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

He will be accompanied by Mr. Richard Rissler, doctor of veterinary medicine, who is Assistant Director of the program and of the Inspection Service.

I might point out that APHIS and the Department of Agriculture have had the responsibility for the humane treatment of animals for a generation, and during that period of time we have sought to make continued improvement in standards; we will continue to seek that. Mr. Hawkins is the official responsible for carrying out these duties within the Department.

Mr. Hawkins.

STATEMENT OF BERT W. HAWKINS, ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY RICHARD L. RISSLER, ASSISTANT DIRECTOR, ANIMAL HEALTH PROGRAMS, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Mr. HAWKINS. Thank you very much, Mr. Chairman and members of the subcommittee.

As indicated, I am the Administrator of the Animal and Plant Health Inspection Service, and I have with me Dr. Richard Rissler, who is my key staff person in charge of the Animal Care Program.

I will apologize once for my voice. I will try to do the best that I can, but I am having a little trouble.

With your concurrence, we will submit the total context of our remarks for the record.

Mr. BROWN. Without objection, it will be made a part of the record, Mr. Hawkins.

Mr. HAWKINS. Thank you, sir.

Since the passage of the Animal Welfare Act in 1966, we have had the responsibility for it, for the administration of it, and I would have to say at the outset that it is one of the more difficult

acts given to us by Congress to administer. The reason for this being that many of the factors that it takes to administer the act are judgment factors, and no two of us can use judgment in exactly the same manner.

Just as one brief example, if one of you gentlemen had a saddle horse and I had one, and you kept yours in a padded stall and I gave mine freedom to roam; I might think that yours was being confined under conditions that were less than humane, and contrary, you might think that the free-roaming aspects of mine allowed him to come into contact with elements that would be very detrimental to him.

I just mention that as one of the reasons why we feel that this act is one of the more difficult. Under current authorities, we inspect nearly all State-owned and privately owned research facilities. These are registered facilities, and they must also submit annual reports to us that have to do with their care and treatment of animals. Each registered facility must report on the conditions and the treatment of their lab animals and any painful research that they are involved in with these particular animals.

As you gentlemen also, I am sure, are aware, Federal facilities are not required to be inspected by us, but we do monitor them and receive annual reports from them as to their care and treatment of animals they are using in their research. One reason for this being that they have their own internal monitoring systems; they have their own veterinarians and have established, in concert with us, the standards necessary to humanely handle animals and keep them as free of pain as possible.

We do try, on an average, to visit each one of these registered facilities at least twice annually. This is not always possible. It is not always really necessary. Again, it is a judgment call with some of our inspectors. If we have a facility that has a long history of being up front, treating their animals very humanely, and submitting good reports, we might only visit it one time in 1 year.

So some people do take us to task and say that we should be visiting them more, but again, this is one of the judgment calls that we do make.

Mr. Chairman, the Department's commitment to accomplish the goals of the Animal Welfare Act have never been greater. In the past 2 years, we have initiated several new initiatives to improve our administration of the act. We have created our own internal system for reviewing what we did in the past and how the program is being handled currently, and on top of that, we are taking a hard look at our program to decide what improvements need to be made.

We have made organizational changes that make us more responsive to not only the public complaints and comments but also to deal more effectively with the weak spots that our internal review indicates. We have established training courses for all of our people that have to work with the Animal Welfare Program.

On May 15-18 of this last year, we had a training course for the animal care specialists, our regional compliance officers, and all animal care coordinators. A total of 42 persons attended that 3-day meeting.

In September we initiated another training session for the veterinarians who actually do the inspection of research facilities. We had a total of 14 at this training course.

We have undergoing at the present time, September 18-21, a training course for the animal care coordinators in the northern region. We have 21 people attending that training course.

Also, in December of this year, we will have a second training course for veterinarians who inspect research facilities. I mention that in passing to show our great concern for trying to do a better job with the authority and responsibility given to us by Congress.

I would also like to mention that since I have been administrator of APHIS, I have placed a great amount of emphasis on the compliance with the law and regulations. We can pass laws and we can administer and promulgate regulations, but without strong compliance, they are a needless waste of activity. We put a lot of emphasis on this. We are reviewing our Compliance Program and have already made very substantive changes in it.

In addition to the internal initiatives that I spoke of, we have increased our cooperation with other Federal agencies as well. We have recently become a member of an Interagency Research Animal Care Committee made up of several of these agencies, two of them being the National Institutes of Health and the Food and Drug Administration.

We think this is important. Since they have the authority to take care of their own animal health care needs and report to us, we can get a dialog going between us and bring all of our animal care activities up to the same level and thereby, we feel, do a much better job of coordination.

Mr. Chairman, the efforts of the Federal community to see that animals used in research receive proper care suggest that these agencies should be able to continue to monitor compliance of their own laboratories. Therefore, we do not see the need to expand on the definition of research facility to include Federal laboratories, in order to make them subject to APHIS registration and inspection.

We feel strongly that it would be a duplication of effort. They have already established their animal care committees and are already meeting with us in concert to try to establish uniform inspections.

We also believe that the bill will increase the enforcement problems. For example, the term "minimum" is not included in the bill as the lower limit for standards of care, and this would require new regulations. The word "minimum" is accepted and more easily defined in a court of law than the suggested change in this bill. It is easier for us to establish minimum levels. We would like to recommend that the term be retained. Similarly, the added requirement of exercise for dogs could cause difficulty in establishment of an enforceable standard. Again, we have different types of dogs—big ones, little ones. What is good for one is not necessarily good for the other. One is a house dog; one is an outside dog. This makes it very difficult to make a judgment that would be enforceable.

Mr. Chairman, my remarks have been short, as you indicated, for time. We would be pleased to answer any questions that you or the subcommittee may have.

[The prepared statement of Mr. Hawkins appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Mr. Hawkins.

Dr. Rissler, did you have any comments you wished to add?

Mr. RISSLER. No, sir; I have no additional comments.

Mr. BROWN. Mr. Hawkins, just a couple of quick questions.

You have some problems with certain aspects of the bill. You did not mention the requirement for the animal care committees in the research laboratories, which is already the practice in the Federal laboratories; nor the data bank for voluntary collection of information on experiments so as to avoid duplicative experiments.

May I take it that you find no strong objections to those provisions of the bill?

Mr. HAWKINS. Yes, sir.

Mr. BROWN. Mr. Roberts, do you have any questions?

Mr. ROBERTS. Yes, Mr. Chairman.

I think the basic concern I have is this: Does the Animal and Plant Health Inspection Service have the wherewithal to actually conduct the necessary surveillance, or should we be in the business of providing some additional funds? What is your budget for the implementation of the Animal Welfare Act?

Mr. HAWKINS. Our budget is \$3.6 million in the upcoming 1985 animal welfare program.

Mr. ROBERTS. In your opinion, Bert, is that adequate to do the job?

Mr. HAWKINS. I am sorry. I was under the impression that you meant what we asked for in the fiscal year 1985 budget. It is currently \$4,865,000.

Mr. ROBERTS. I am sorry, I am confused on that. What were the figures again?

Mr. HAWKINS. The current 1984 budget is \$4,865,000.

Mr. ROBERTS. So it is not \$3.6 million but \$4.8 million?

Mr. HAWKINS. That is right.

Mr. ROBERTS. We increased that, as I recall.

Mr. HAWKINS. Yes, sir; I was speaking of the 1985 budget request.

Mr. ROBERTS. Is this budget adequate, in your view, to do the job? We will hear panelists later, obviously, who think that we do not have adequate funds, and some of the adjectives and adverbs I won't get into at this particular time. But is this funding adequate?

Mr. HAWKINS. Yes, sir; we feel it is adequate, and the reason being that Rome wasn't built in a day, and all people's ideas of care of animals won't be changed in a day. We could put an army of people out there with an abundance of funds to support them, and we would still have infractions of the act.

I think it is an educational process that we must go through, and with the changes that we are implementing, I feel, Mr. Roberts, that we do have sufficient funds and personnel.

Mr. ROBERTS. That was my next question. How many personnel are involved?

Mr. HAWKINS. I am going to ask Dr. Rissler to answer that. I know of some figures, but since he is here, I would rather he answer.

Mr. RISSLER. Of our veterinary medical officers field force, approximately 300 of them are involved in animal welfare activities. In addition, we have approximately 200 that we call animal health technicians. This also includes our compliance officers.

So in round figures, about 500 of our field force spend a percentage of their time on the animal welfare program. This means they do not spend full time on the program. They also do other things.

Mr. ROBERTS. Pardon me for interrupting, but in terms of this number, how many are veterinarians?

Mr. RISSLER. Approximately 300 of these people are veterinary medical officers. The remaining 200 are animal health technicians who are laymen.

Mr. ROBERTS. We have a quorum call, Mr. Chairman. I have no further questions.

Mr. BROWN. Mr. Staggers, do you have any questions?

Mr. STAGGERS. Yes; Mr. Chairman, I will take as short a time as I can.

I understand that there is a GAO study under way right now and that the preliminary reports would indicate that there is very little enforcement of the Animal Welfare Act to date.

I hear you respond to Mr. Roberts that in fact you do have adequate funding. I guess the issue then is, can we enforce the act, or can we enforce the amendments? It would appear there is an enforcement problem here. How do we respond to that?

Mr. HAWKINS. Your point is well taken. It is an enforcement problem, and as I indicated in my remarks, we have made a substantial inroad in the area of compliance.

I have taken a strong stand on this. Again, some people are not too aware that we are following up on the compliance issue. We have recently been involved in many violation cases for which you gave us the authority to impose civil penalties. We are citing people very regularly. We are publicizing these facts, and we are going to have compliance not only in animal welfare but in the other programs that Congress gives us authority and responsibility for.

Mr. STAGGERS. So your point would be that we don't need to amend this; we don't need more funding; we don't need more personnel; just give you more time and you will be able to do the job? Is that your bottom line?

Mr. HAWKINS. That is correct, sir; because, as I mentioned earlier the training that we are presently involved in, the establishment of a full-time coordinator, and a coordinator in each State responsible to the AVIC of that State, are making substantial inroads in compliance with the regulations.

Mr. STAGGERS. I guess your point would be that the GAO study should be ignored for at least how long? How long can we expect your internal—

Mr. HAWKINS. We will never have 100 percent compliance, sir. There will always be some violators that will have to be identified by those who care. We cannot police the total United States all the time.

I feel definitely that given another year, with the action that we have taken, you will see substantive changes in our responsibility for carrying out the authority that you have given us.

Mr. STAGGERS. So if we come back next year and it has not happened, then you will be right behind us saying that you need more money, more funding, more personnel, amendments to change the law, and so forth?

Mr. HAWKINS. If it is identified that that is the problem, yes, sir; we would. There may be other things that would make them more important at that time, but yes, I would have to agree to that statement.

Mr. STAGGERS. Thank you.

Thank you, Mr. Chairman.

Mr. BROWN. Mr. Hawkins, if I may just emphasize something you have said here, I think what you are saying is that this is not a system which will ever be perfect, and it will continue to require input from the public and input from voluntary organizations such as animal care committees in the laboratories.

Mr. HAWKINS. Yes, sir; we are very appreciative of their identifying problems, because they are broadly scattered across this Nation. They are a big help to us in our enforcement activities.

Mr. BROWN. Thank you. We appreciate that.

Mr. Hawkins, I am going to excuse you at this time. We have a quorum call on, and as soon as we return from answering the quorum call, I will call Dr. Wyngaarden from the National Institutes of Health.

Mr. HAWKINS. Thank you, sir.

Mr. BROWN. The subcommittee will be in recess for about 10 minutes.

[Recess taken.]

Mr. BROWN. The subcommittee will come to order.

We will next hear from Dr. James B. Wyngaarden, Director of the National Institutes of Health, who is accompanied by Dr. William E. Raub, Deputy Director for Extramural Research and Training.

We very much appreciate your being here, and you may proceed with your testimony, Dr. Wyngaarden.

STATEMENT OF JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, ACCOMPANIED BY WILLIAM E. RAUB, DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH AND TRAINING

Mr. WYNGAARDEN. Thank you, Mr. Chairman and members of the subcommittee.

I am pleased to present to you this morning the views of the National Institutes of Health on legislation concerning the care and treatment and use of research animals, and to describe to you some of the activities we have undertaken to address this issue.

Let me begin by stating our general views on H.R. 5725. We think the bill reflects a good understanding of some of the fundamental concerns and needs of the biomedical research community. We agree with its goal; namely, a system that provides for effective oversight of the use of animals in research; close involvement of institutional committees with the animal care and use programs of those institutions; training of administrators, scientists, and technicians in humane animal care; availability of information about po-

tentially useful methods and models which might reduce the number of animals needed for research; and adequate and effective communication with the public about the use of animals in research.

We do not agree, however, with the premise that new legislation is needed to achieve that end. We are convinced that under existing law and administrative authority, we are working effectively in pursuit of goals I know we share with you, others in the Congress, and the public.

The Animal Welfare Act administered by the Department of Agriculture applies to research institutions. We believe that its current authority is satisfactory and allows the USDA to change procedures and standards as necessary.

In addition, the Public Health Service has used its authority to promulgate policies and guidelines relative to animal welfare for its own awardees. There is sufficient flexibility under that authority to modify this policy as needed.

I would like to describe briefly our current policies and procedures relative to awarding institutions where animals are used in research. Under current PHS policy, as a condition of a PHS award for research in which vertebrate animals are used, the awarding institution must provide written assurance that it has established an animal care committee to oversee care and welfare of animals used in research.

Every institution for which we provide funds for vertebrate animal research in fact has such a committee, composed of a minimum of five members, at least one of whom is a veterinarian. Every institution using vertebrate animals in research must include in its written assurance, which is kept on file with the NIH Office for Protection from Research Risks, a statement that the institution is committed to following the principles and guidelines of the NIH Guide for the Care and Use of Laboratory Animals.

About one-third of these institutions have accreditation from the American Association for Accreditation of Laboratory Animal Care—the best evidence, we believe, of full compliance with our guide. The remaining institutions are either in full compliance with the guide, as determined by their animal care committees, or are working toward full compliance.

In terms of compliance with our PHS animal welfare policy and with our guide, NIH relies on a system of written institutional assurances. We have not felt the need to establish a system of routine inspections, a costly system which would needlessly duplicate activities of other agencies.

Because of our awareness of congressional and public concern, we have initiated a number of activities designed to evaluate our assurance system, tighten our animal welfare policy, and enhance our communications. I would like to describe some of these.

In the spring of 1983, we participated with the Food and Drug Administration and the USDA in the development of a memorandum of understanding designed to increase interagency communications with respect to deficiencies related to animal care and treatment. We expect that communication will continue to improve because we, the FDA, and the USDA have a commitment to improve it.

For more than a year, we have shared information among these agencies. This has improved compliance while reducing the cost of inspections.

Over the summer of 1983, NIH site visited 10 randomly selected awardee institutions. The purpose of these visits was to discuss the viability of our own assurance statement system. The visits were organized by the NIH Office of Extramural Research and Training and included members of intramural and extramural staffs and outside consultants, including veterinarians.

There were two significant findings of the site visits: no abuses of animals were found, and our assurance statement system and our animal welfare policy were determined to be effective, although not perfect.

Incidentally, Mr. Chairman, the findings from this series of site visits are summarized by Ann Landers in the Washington Post this morning, and with your permission, I would like to insert this into the record.

Mr. Brown. Without objection, it will be made a part of the record.

[The material follows:]

Dear Readers:

Do you remember the abusive letters I received because I printed a column in support of animal experimentation? I listed many diseases that never would have been conquered had medical researchers been denied the right to use animal models.

I thought you might be interested in the following information:

In 1983, the National Institutes of Health published notices about their plan to conduct site visits to institutions receiving government funding. The purpose was to ensure that the animals used for research were being treated humanely.

Between June and September the following institutions were visited:

Brandeis University, Waltham, Mass.

New York University, New York City.

Children's Hospital of Pittsburgh. Bethune-Cookman College, Daytona Beach, Fla.

Ann Landers

Northwestern University, Evanston, Ill.

University of Texas-Austin, Austin, Tex.

St. Louis University, St. Louis.

LDS Hospital, Salt Lake City.

Syntex Research Division, Palo Alto, Calif.

University of Washington, Seattle.

The site-visit teams consisted of a veterinarian, a biological scientist currently working with animals and an NIH scientist-administrator. Nonfederal consultants were included to guarantee impartiality.

The results were as follows: No incidents of animal abuse were observed. At all institutions, a full- or part-time veterinarian had been appointed. In most cases the appointee had advanced training in laboratory animal medicine.

The areas where most animals were kept met the requirements and care was graded from "adequate to excellent."

It should hearten my readers to know that installations where animal research is being conducted will receive no government funding unless they meet the high standards set by the National Institutes of Health.

Mr. WYNGAARDEN. As a result of our site visits, we made several decisions. First, we decided to continue a small program of random site visits. Indeed, another series of five was completed about 3 weeks ago. Again, these visits were not to duplicate or replace the unannounced inspections of the USDA Animal and Plant Health Inspection Service. They followed a carefully designed protocol to evaluate the effectiveness of our assurance system. They also emphasize to awardee institutions that their assurance statements are living documents and must accurately reflect the status of the institution's animal care and use programs.

Second, we proposed a revision of the PHS policy on animal welfare, strengthening the policy in accordance with suggestions by site team visit teams and suggestions made to us through various means by the Congress and the concerned public.

We published the proposed revision in a special edition of the NIH Guide for Grants and Contracts in April 1984 and solicited public comment. We have received a great deal of comment, and we are currently analyzing those replies.

Let me highlight a few aspects of the proposed revision that relate particularly to H.R. 5725. Our proposal would require that institutional animal research committees include a member not affiliated with the institution and also a nonscientist and that the committees be involved in the review of each proposed research protocol. One objective of this review would be to determine that the care and use of the animals is in compliance with the guide and other applicable laws and regulations.

The proposed revision would also require a more frequent updating of institutional assurance statements and a specific timeframe for complying with the NIH guide for those institutions that are not already in compliance.

Next, we initiated an educational campaign which includes a 2-day national symposium, already held, and a series of regional workshops dealing with PHS animal welfare policy, directed primarily to institutional animal research committees and research administrators.

Concern about animal welfare frequently leads to discussion of the extent to which the use of animals can be reduced. The NIH Division of Research Resources has funded a series of workshops, sponsored by the National Academy of Sciences, on the subject of what are sometimes termed "alternative" or "adjunct" methods of research.

The workshops, which were completed in late summer, brought together scientists from many disciplines to discuss such topics as cell culture methods, mathematical and computer modeling, and the use of lower organisms in research. These workshops served to make many more scientists aware of various research methods and models that might now or in the future be available for particular kinds of research activities.

It is expected that the forthcoming report of the National Academy of Sciences will include recommendations regarding the funding of research and the development of promising models and methods. NIH is funding such research already and is ready to expand its efforts into promising new areas.

In closing, Mr. Chairman, I want to say that we are convinced that researchers, with rare exceptions, respect animals as unique and valuable resources, use them prudently, and do not abuse them.

Further, we at NIH are committed to the humane care and treatment of research animals and to their appropriate, thoughtful, and careful use. The same commitment is expected of our awardee institutions.

Thank you, Mr. Chairman. I will be pleased to answer any questions you may have.

[The prepared statement of Mr. Wyngaarden appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Dr. Wyngaarden.

Did you have anything additionally, Dr. Raub?

Mr. RAUB. No, sir, I don't.

Mr. BROWN. Mr. Staggers.

Mr. STAGGERS. Thank you, Mr. Chairman.

In your statement, you mentioned that you do not agree with the premise that new legislation is needed to achieve the goals that we all are pursuing, that you are convinced that under existing law and the administrative authority you can in fact achieve effectively the goals that we all are pursuing.

I would bring your attention to the GAO study I mentioned earlier with the witness that preceded you, that the preliminary reports indicate that there is very little enforcement of the Animal Welfare Act, and that there may be some abuses, and ask for your comments.

Mr. WYNGAARDEN. I think, with respect to the use of animals in research, that the compliance with the guidelines is general throughout the research community and that the periodic revision of these guidelines as problems are identified does serve to improve the care of animals.

There is no difference of opinion whatever concerning objectives. We think that the periodic site visits that have been conducted recently will tune up the system; they will convey a message to the awardee institutions that we take seriously the compliance, as they do, but that we also will, from time to time, check on our interpretation of compliance and stimulate their improvement where there may be deficiencies.

We also think that the revision of the guidelines incorporates many of the proposals that are in this bill, the ones that we feel particularly valuable. I could cite those specific features if you would like where the proposed guidelines are in consonance with this proposal.

Mr. STAGGERS. Let me ask you, with some of the perceived abuses, when can we start to expect—as you say, under existing law and administrative authority—that we will see the results? Are we seeing them now? Is that your perception?

Mr. WYNGAARDEN. I think we are seeing them now. It is ongoing. Where there are deficiencies or specific allegations of abuse, we have a system and a procedure for dealing with these complaints, which includes working with the institutions to identify the validity of complaints and, if there is some validity, moving to the next level of investigation, which may include site visits, if that is indi-

cated, to the institution. If, indeed, there is a serious degree of non-compliance, we have certain remedies available to us in suspending the award, terminating the award, or even withdrawing the assurance from the institution. That last has never been necessary.

Mr. STAGGERS. At what point, in terms of time, do we reach where we do need to change the legislation, if in fact we don't perceive the results coming forth? I mean, next year, if in fact we have people testifying that there are the abuses, that we should start looking at it next year or 2 years from now or what?

Mr. WYNGAARDEN. I don't really find it possible to put a time-frame on that probably because I don't really agree with the implication that there is widespread abuse of the use of animals in research that would require such legislation.

Mr. STAGGERS. Let me switch tracks. What type of justification does a scientist need to make in proposing an experiment when he is going to use animals now?

Mr. WYNGAARDEN. The first line of approval involves the animal care committee at the institution, and if that approval is forthcoming, the application comes to the National Institutes of Health, where it is reviewed by a study section for scientific merit and technical feasibility, and if animals are proposed for use, the report of that committee in either approving or disapproving the proposal must include a statement about the use of animals.

We find that that is a powerful assurance that the guidelines of the Public Health Service are indeed being met.

Mr. STAGGERS. For a layman, what does that mean? I mean, what can I look at, what justifications? I understand the procedure that you go through, but what are the justifications?

Mr. WYNGAARDEN. The justification has to do with the review at the local level for the appropriate care and use of those animals, and at the level of the scientific review at the NIH, for the need for use of animals in this particular research proposal.

Mr. STAGGERS. So there is no overall review; it is totally at the discretion of the local level whether in fact—

Mr. WYNGAARDEN. No; at the level of the National Institutes of Health, there is the review of the research proposal to see that the use of animals is appropriate, that the species are appropriate, the numbers are appropriate, and that, indeed, there is not a better way to do the research.

There must be an extensive justification in the proposal for this work related to other work which has been done, which then approaches directly the subject of unnecessary duplication. If, in the view of the scientists reviewing this proposal, this is strictly duplicative work, it would not be funded.

Mr. STAGGERS. Thank you, Mr. Chairman.

Mr. BROWN. Dr. Wyngaarden, generally speaking, your statement presents an encouraging analysis of the situation with regard to research using live animals; yet we still find examples, and they are in very prestigious institutions, where there seems to be some lack of adequate standards for the use of laboratory animals.

We have had well publicized incidents in my own State at the University of California and Stanford and other places. It may well be that there is no strictly institutional way in which you can achieve perfection or perhaps even reasonably satisfactory stand-

ards. For example, assume that APHIS makes their annual two visits per year but the inspector is a little careless and does not visit all the facilities; the local animal care committee does not meet very often and does not get around to seeing some of these things. You can have, then, situations in which the standards were not being met, and, obviously, this is what happened in a number of cases.

What recourse do we have when there is some failure in this institutional or bureaucratic system to maintain the kinds of standards which you and I and other reasonable people would like to see maintained?

Mr. WYNGAARDEN. Yes, Mr. Chairman. Let me point out that we fund about 17,000 investigator-initiated awards, and about 40 or 45 percent of those involve animals.

Yet, since September 1981, 3 years now, the NIH Office for Protection from Research Risks has conducted 11 investigations of allegations of noncompliance with the guidelines or potential abuse of use of animals. In nine of those investigations, the allegations reached us by individuals who were not directly concerned with the research. In three instances, onsite visits were conducted. Five investigations yielded no evidence of noncompliance. In three, some deficiencies were found and corrective measures taken. In one, evidence led to the conclusion that there was material failure to comply with the policy and the grant was terminated.

I submit that those are minuscule figures compared with the total universe of research that we support. We do have the remedies in the case of noncompliance that I have mentioned. We can suspend an award until the institution or laboratory is in compliance. We can terminate the award if necessary. We could, indeed, withdraw the assurance of the entire institution, but that has never been necessary.

Mr. BROWN. I have looked at this Ann Landers column that you referred to; I have it in front of me, as a matter of fact. I am told that some of the institutions on this list which you found adequate to excellent, that USDA inspectors found major deficiencies in them.

Do you feel that there is any possibility that that could be the case?

Mr. WYNGAARDEN. Let me ask Dr. Raub, whose office conducted these site visits, to speak to that if he would.

Mr. BROWN. While you are at it, were these announced or unannounced site visits?

Mr. RAUB. These were announced site visits, sir.

Part of the preparation for the visits was the examination of USDA reports on those institutions, so we had some cues as to where there might be particular problems.

Our primary thrust was to examine the total management system and the facilities within those institutions, looking for the kinds of systemic strengths or weaknesses that would serve, in the first case, our purposes over the long term, or for which some specific remedies would be needed.

In our judgment, all of the institutions involved were in compliance with their statement of assurance to us. In a few instances, we were able to identify areas where improvements were possible,

and we shared those observations with the institutions and will be working with them to ensure that there is followthrough.

Mr. BROWN. Well, I am not obsessed with the idea that we are going to achieve perfection here. I am just concerned that we achieve the highest standards that are reasonable under the circumstances.

Without objection, I will be allowed to continue for an additional couple of minutes, even though the red light is on.

It came to my attention that we had a situation at the University of California at Berkeley where the psychology department was conducting some live animal experiments, and the supervising veterinarian at the university was so dissatisfied with the situation that he refused to sign the appropriate reports. Yet the deficiencies continued, anyway.

Now, I am not prepared to feel that the psychology department is composed of evil, lawbreaking men, but there is something wrong with the system there. It could be lack of funds to accomplish what is needed to be done or lack of motivation; I don't know. But how do you analyze a situation like that, Mr. Wyngaarden?

Mr. WYNGAARDEN. We stay in very close contact with that particular situation that you mentioned. Dr. McCarthy's office, the Office for Protection From Research Risks, has tracked it, as has Dr. Raub. We have just this week discussed the matter. I understand there have been substantial improvements at the University of California in Berkeley, that they are now in compliance, and that the veterinarian who had earlier reservations has signed the statements of compliance.

Mr. BROWN. Did you use some persuasion, threat of withholding grants, or something like that?

Mr. WYNGAARDEN. I would have to ask Dr. Raub whether it reached that level.

Mr. RAUB. It did not reach that explicit stage, sir, but we conducted, as I recall, two separate site visits, the second one in conjunction with a representative from the USDA. We were focusing, specifically, on the findings of the USDA, the concerns of the local veterinarian, and concerns and allegations that had been expressed by citizen groups in the area. We came away satisfied from the second visit that the institution was clearly on the track and committed to remedying the kinds of structural and communications deficiencies that had existed before.

We have a negotiated assurance with the institution that we intend to follow closely, and we are confident that the institution will reciprocate.

Mr. BROWN. I have no theory of an evil conspiracy at the University of California. I like the University of California. I am an alumnus of it, myself, and I think it is a great institution. But it may be that they have a situation somewhat like we have here in Congress with our Ethics Committee. We don't always diligently pursue some of the allegations that we might, just because we are all part of the same club, you know, institutional framework.

It is that kind of problem that I think we need to be concerned about, and where your reassurances don't always satisfy me that we have achieved the kinds of results that we ought to achieve.

Are you concerned about that, Dr. Wyngaarden?

Mr. WYNGAARDEN. I think it is a very valid point, and it is a matter of concern, but I do think that the performance record of the NIH in this respect indicates that we can be firm and forceful when the situation requires it, even to the point of terminating support when necessary.

Mr. BROWN. Generally speaking, though, the situation only requires that when there is a loud public hue and cry. Isn't that the case?

Mr. WYNGAARDEN. No; I would certainly agree that our concern is intensified when the public is greatly concerned. But we have also investigated many complaints that have not had much newspaper coverage.

Mr. BROWN. That is reassuring, and again, I propound this line of questioning not because of any conspiracy theory but because I am quite familiar with human nature and how it works, and I am concerned that we do everything we can to create systems which will help to overcome that as much as possible.

Thank you very much for your testimony. If you would care to submit any additional material after you have reviewed the record, we would be pleased to have that.

Mr. WYNGAARDEN. Thank you very much, Mr. Chairman and Mr. Staggers.

Mr. BROWN. We are now ready to call our first panel of witnesses, which will include Dr. Van Hoosier, Dr. McArdle, Dr. Geelhoed, and Dr. Randall. In addition, I have asked Dr. Frank Loew to appear on this panel as a substitute for Dr. Jean Mayer, president of Tufts University, who was unable to come but asked Dr. Loew to appear in his behalf. Dr. Loew is dean of the College of Veterinary Medicine at Tufts University.

STATEMENT OF FRANKLIN M. LOEW, DEAN, SCHOOL OF VETERINARY MEDICINE, TUFTS UNIVERSITY

Mr. LOEW. Mr. Chairman and subcommittee members, thank you for the opportunity of appearing before you.

As the chairman noted. I am dean of the School of Veterinary Medicine at Tufts University in Boston, and I am here to speak in support of this proposed legislation and to give you my assessment of the effectiveness and enforcement of the current Animal Welfare Act and its regulations.

I also bring you the greetings of the president of Tufts University, Jean Mayer.

I am a member of many national scientific organizations such as the Commission of Life Sciences of the National Research Council, National Academy of Sciences. As well, I recently completed a 3-year term as chairman of the Institute of Laboratory Animal Resources of the National Research Council, National Academy of Sciences.

I am chairman of the Board of Trustees of the Boston Zoological Society and president-elect of the Association of American Veterinary Medical Colleges.

In every way, issues affecting animals and their care constitute my total occupation. But I also hold a Ph.D. degree in addition to

my veterinary degree, and I have carried out research in which animals were studied.

As a scientist, therefore, I am a member of several scientific societies such as the Society of Toxicology and the American Institute of Nutrition, a constituent society of FASEB, the Federation of American Societies for Experimental Biology.

But I do not speak to you today representing the official views of any of these organizations and societies. I wish to give you my own personal, professional, and scientific opinion. This opinion is based on 20 years in this field, most of it since the passage of the original Laboratory Animal Welfare Act in 1966.

Concern, Mr. Chairman, about animals of all kinds has never been higher in this country. But as usual, in controversy, where you stand depends on where you sit. That is why I have chosen to represent only my own views today.

H.R. 5725 deserves acceptance if not support by all scientists who occasionally or frequently must study animals in the course of their important work on behalf of human or animal health. First, what will the proposals not do? The proposed amendments will not measurably affect the ability of scientists to carry out well planned animal studies, in my opinion. Indeed, these proposals would not restrict even painful research providing that appropriate review and accountability at the local institutional level takes place—review which this bill directs to take place at the local institutional level by local people, not by Washington-based inspectors.

Thus, those who come today to talk about total antivivisection or, on the other hand, about bureaucratic big brother watching us, will have to look elsewhere, not here. Such extreme and unacceptable approaches should never, I hope, be considered as acceptable by the Congress.

But H.R. 5725 is far from extreme. Its passage would result in little that is different from currently proposed changes in the U.S. Public Health Service, NIH, requirements of its grantees using animals. More about that in a moment.

Science, throughout history, has always been a product of the culture and society which support the scientific enterprise. American culture and society in these last 20 years of the 20th century clearly have expressed a desire for greater accountability from all scientists, including those who use human subjects or recombinant DNA or vertebrate, nonhuman animals.

I find it neither surprising nor upsetting that this is happening. It was predictable. It was inevitable, and in my view it is decent and proper.

You will hear today from some critics that these proposed amendments are too weak and mealy-mouthed, and you will hear from others that they will be costly to implement, or too bureaucratic, or invasive of the principle of free scientific inquiry.

I disagree with these criticisms. The tenor of H.R. 5725 is just about right in reflecting informed public criticism as well as the conclusion of many enlightened scientists, in my opinion. Criticisms of these proposals on the basis of cost are particularly weak, I think, in view of other research grant-borne costs such as word processors, travel to meetings, technical and professional salaries, or even the cost of the animals themselves.

The chairman and subcommittee members will know that the National Institutes of Health is currently proposing changes in its grantee requirements for animal care and use. I support those proposed changes, also. The needs of human medical, veterinary medical, biological and agricultural research are simply too great to risk a loss of public faith, congressional faith, in the research enterprise.

I hope that appropriate consultation between the Public Health Service and the USDA's Animal and Plant Health Inspection Service will take place to ensure consistency or complementarity in the eventual regulations, guidelines, assurances, and procedures.

In my opinion, the study of human and animal subjects continues to be a crucial component of life science research and teaching throughout the world. Careful periodic revision of NIH requirements and USDA regulations will, I think, go far in preserving the freedom to use these approaches when appropriate. But such revisions must be well thought out, as these are, and not so frequent as to make compliance or planning for compliance futile for our universities, industrial laboratories, or research institutions.

I would like now to briefly assess the current APHIS enforcement of the Animal Welfare Act. In a word, it has been uneven. The program suffers, in my opinion, from a lack of adequate funds, a too-small professional and technical staff which ranges in competence and interest in this act's requirements from excellent to marginal, and from internal legal support which is stretched too thinly.

I understand that the GAO will be or has reported to you on this program. The U.S. Department of Agriculture is among the most distinguished of American Federal Departments, from the days of the old Bureau of Animal Industry to today's superb and well-run laboratories, to the vital financial support provided to our experiment stations and land-grant universities. It is a part of all of our lives.

But it is not always perfect and, as such, is often a scapegoat for all sorts of real or imagined problems. The Animal Welfare Act is, by and large, a good act, and its regulations are, by and large, good regulations. Your proposed changes will make it even better, in my view.

But it will not succeed without a commitment at the highest level, without adequate funding, without enough properly and regularly trained veterinary medical and compliance officers. After all, there are over 1,100 registered research facilities in this country. I urge you to assess the situation, with the help of the GAO, and act if you agree.

As requested, I have refrained from discussing many other aspects of animal experimentation, but these have been considered in hearings held in 1981 by Mr. Walgren and in 1982 by Mr. Waxman. There is a good and complete record.

In conclusion, Mr. Chairman, many of my fellow scientists, physicians, dentists, and veterinarians across the country believe that a sound, properly enforced law protects not only the animals but also scientists and the public interest in good science.

Strangely, it is difficult for many of us to say this publicly, for there can be an orthodoxy in science just as in antiscience. Where you stand really does depend on where you sit. I sit here speaking

for myself and what I believe to be necessary for the maintenance of continued public confidence in and support of the American scientific enterprise.

Thank you, Mr. Chairman.

Mr. BROWN. Thank you very much, Dr. Loew. I appreciate your statement and your willingness to substitute at the last minute for Dr. Mayer.

I should reiterate what I said at the beginning, that members of the panel will hold a variety of different views on this subject, and this has been deliberate in order that we could, hopefully, create a dialog here. We hope that everyone will seek to broaden his outlook on this subject during the course of the hearing.

Dr. Van Hoosier, we would appreciate your testimony now. Dr. Van Hoosier is from the Division of Animal Medicine, School of Medicine, University of Washington, and he represents the National Association of State Universities and Land-Grant Colleges, the American Council on Education, and the Association of American Universities. That is a pretty heavy load, Dr. Van Hoosier.

STATEMENT OF GERALD VAN HOOSIER, JR., PROFESSOR, DIRECTOR, AND ATTENDING VETERINARIAN, DIVISION OF ANIMAL MEDICINE, SCHOOL OF MEDICINE, UNIVERSITY OF WASHINGTON, ON BEHALF OF THE NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND-GRANT COLLEGES, AMERICAN COUNCIL ON EDUCATION, AND ASSOCIATION OF AMERICAN UNIVERSITIES

Mr. VAN Hoosier. Thank you, Mr. Chairman. It is not nearly as heavy as what your load here is.

Mr. Chairman and members of the subcommittee, my name is Gerald Van Hoosier. I am the attending veterinarian and professor of animal medicine at the University of Washington. Among my professional activities is included a tenure as chairman of the American Association of Laboratory Animal Care, the independent accrediting body for this Nation.

Thank you on behalf of the Joint Committee on Health Policy of the Association of American Universities, the American Council on Education, and the National Association of State Universities and Land-Grant Colleges for the opportunity of appearing before your subcommittee this morning to discuss an issue of major concern, the use of animals in research.

I would be remiss, Mr. Chairman, if I did not take a few moments of my allotted time to note some reluctance on the part of our universities to raise questions about this legislation, given your extraordinary record in Congress these past few years in behalf of scientific research.

We see this bill as a thoughtful attempt to address important issues about the care and treatment of animals in research. That objective is laudable, and we are prepared to try to assist in making it succeed. We take this opportunity, however, to state some basic principles.

First, Mr. Chairman, we believe, as you do, that wise legislation should be based on as much information as may be gathered on the subject in question. During almost this entire Congress, both the

House and Senate committees responsible for biomedical research have had pending a proposal for an 18-month study, conducted by an organization like the National Academy of Sciences, to look into all aspects of the use of animals in research and to make recommendations for such legislation as may be needed.

Some of our colleagues in the animal welfare community have said that studies are a stall. Had we full support from all sides of this issue on that study, it could have been completed by this time.

We maintain that absent such a study, any proposed legislation is subject to responding to mistaken perceptions that could require legislative amendments after avoidable problems have been generated.

Second, the National Institutes of Health is engaged in the consideration of a revised set of guidelines governing the use of animals in research. All interested parties were invited to comment on these proposed guidelines at three public hearings this past year. The final product will represent a balanced approach to this complex issue. We question whether legislation at this time, until those new guidelines are finalized and tested in the field, is prudent.

Differences between these guidelines and the legislation, however unintentional they may be, could cause confusion and delay reaching precisely the objective called for by the animal welfare communities.

As a consultant to this committee for revision of the guide, I can personally assure you that the current draft does have some significant inconsistencies with this proposed law.

Third, we believe that it has been generally understood by the Congress and the general public that animals are used in research because it is necessary in order to improve the health of humans and animals. While many of these are familiar to you, I call to your attention a presentation prepared by the California Biomedical Research Association citing the role of animals in important medical progress such as acquired immunodeficient disease, diabetes, hypertension, and several others. Copies of this will be made available to your committee.

While adjunct methods have been developed in recent years and the numbers of animals used in research decreased, fundamental elements of biomedical research will always require the use of animals. We do not believe the word "alternative" is reasonable. It is not fair nor accurate to hold out the promise that there are or will be research substitutes for animals, other than human beings.

In addition, it is important to note that such adjunct methods typically are developed through the conduct of research, not through research on methods of research. Congress, representing the citizens, wants better forms of heart surgery, wants new disease-preventing vaccines, wants new cures for old diseases.

It would seem appropriate when there are all sorts of attacks on the use of animals in research that the Congress, on behalf of the Nation, state as a matter of public policy the reality that if we are to make continuing progress in the Nation's health, the use of animals is imperative. It would help, too, to have the Congress denounce recent behavior, sometimes criminal in nature, to disrupt centers of science research because animals are being used.

Mr. Chairman, I am a veterinarian and a scientist, and like my colleagues in this profession, I have dedicated myself for the past 27 years to the care and treatment of animals. I would not be associated with any enterprise in which animals were treated carelessly or indifferently, where pain was not prevented wherever possible or not treated if possible.

It should be understood that animals used in research must be healthy and cared for if the research conducted is to be reliable and useful. Allegations of general or broad spread mistreatment of animals in research are devoid of factual basis.

While we operate in restricted circumstances, with restricted funds, improvements cannot only be made but are being made regularly at academic health centers where research is conducted using animals. Such improvements in facilities are necessary to the science and for the humane and proper care of animal subjects.

Nevertheless, these improvements require resources that are not always available. The committee is aware of the limits of such resources and the legitimate claim of many to them. A mandate to provide state-of-the-art facilities for research animals without funds to accomplish this would require a shifting of resources from other, perhaps equally essential, functions.

We all know that bricks and mortar do not an institution make. In addition to funds for facilities, there are real needs for funds for training. There are just not adequate people trained in the field of laboratory animal medicine to staff adequately all the institutions in the United States. We need additional facilities for the diagnosis of laboratory animal diseases. We also need more research on those diseases we do not yet understand and know how to prevent in laboratory animals.

It is not difficult to find ways to significantly improve the application of current standards. As you know, APHIS is mandated to conduct inspections of facilities using animal research. Little else would be needed to achieve this congressional goal of better oversight than to provide APHIS with adequate funding annually.

There are too few inspectors, and too few of them able to devote themselves to this area of animal welfare. Frequently, it is a very minor part of their overall activities.

It may be well to add that we do not need more legislation, just more support for inspection and training. I would add here that the accreditation mechanism in effect, which this bill does not mention, has had a tremendous impact for good on animal care programs.

We believe that the current Animal Welfare Act, along with NIH standards, is adequate to meet reasonable standards of care for animals in research. New legislation may not be necessary. In addition, there is no reason to believe that the new legislation would be enforced any better than present law, absent adequate support for APHIS.

We will not undertake, in this testimony, to offer a detailed analysis of various points in the proposed legislation that we would like to have clarified and modified. If it would prove helpful, we will submit such an analysis for the record.

There are, however, a few issues that are of particular concern. Given the red light, I will submit the text of this for the committee

but would particularly emphasize that section 4(c) would certainly reduce current prohibitions on interference in the actual research and conduct of experiments. This, we feel, is a matter of special concern.

Thank you, Mr. Chairman. I will be glad to answer any questions you may have.

[The prepared statement of Mr. Van Hoosier appears at the conclusion of the hearing.]

Mr. BROWN. Thank you, Dr. Van Hoosier.

We will ask you to make the analysis that you suggested. There will be no big hurry about it, but we do invite you to consider that and to submit it to the subcommittee at a convenient time for you.

Next, Dr. John McArdle, who is director of laboratory animal welfare for the Humane Society of the United States.

STATEMENT OF JOHN McARDLE, DIRECTOR, LABORATORY ANIMAL WELFARE, THE HUMANE SOCIETY OF THE UNITED STATES

Mr. McARDLE. Mr. Chairman, I am Dr. John McArdle, director of laboratory animal welfare for the Humane Society of the United States. I am here today to represent our 300,000 constituents.

As to my personal background, I have a doctorate in anatomical sciences from the University of Chicago and approximately 10 years of experience working with laboratory animals, including experimental surgery.

My detailed testimony has been submitted for the committee, including an appendix itemizing the situation at the University of California at Berkeley. What I would like to do this morning is to highlight specific areas of concern, initially talking about the enforcement program with APHIS and then talking about ways I believe that this legislation will help clear up those problems.

Mr. BROWN. Dr. McArdle, we will include the full text of your prepared statement in the record.

Mr. McARDLE. Right. I just simply have notes here. I am not going to read my testimony.

Mr. BROWN. We would appreciate it if you would be as restrained as the two previous witnesses.

Mr. McARDLE. I intend to be.

Particularly with APHIS, we think the problems have to do with the inspectors, that there is a need for a consistent interpretation of inspection and enforcement requirements in the field, and that they, in fact, are inadequately trained.

Dr. Robert Crawford, at the USDA, recently noted that we have inspectors who have no interest in inspecting; we have some who have no training or have inadequate training. I believe there is a problem with funding, as has been mentioned.

Areas within the United States, such as California, often receive less than one inspection per year. We understand that some institutions in fact have not been inspected in several years.

We are particularly concerned about the issue of funding. At a time when they claim that there is not enough money to hire adequate numbers of inspectors to do adequate inspections, the GAO study found that last year they still managed to produce a surplus

of \$700,000, which was spent on a fleet of new cars for their inspectors.

We are particularly concerned because we received word this year, due to a reallocating of Animal Welfare Act inspectors for the State of Pennsylvania, that funds are piling up due to a lack of Animal Welfare Act inspections, and they are producing another surplus this year somewhere in the vicinity of \$200,000 to \$300,000. We are wondering exactly whether or not that is going to mean another fleet of cars. We also wonder how seriously they take this issue, since they are in fact having surplus money this year.

With regard to enforcement, there is evidence that contested violations against dealers have remained pending in the Office of General Counsel for periods of 2 or more years. We are concerned about that.

As you mentioned, there is a situation at Stanford University. The Peninsula Humane Society in Palo Alto is presently in court seeking judicial review of the failure of the Palo Alto Veterans' Administration Hospital and Stanford University to comply with provisions of the Animal Welfare Act and for APHIS to fail to enforce them.

I would like to just itemize, I think, the situation at Berkeley because it is indicative, I think, of the problem. Substantial and illegal conditions have existed at that university since at least 1974 when they were first documented. As was mentioned, the campus veterinarian refused to sign the compliance forms for the years 1980 and 1983.

Last winter, several thousand animals died at that facility due to repeated malfunctions of the heating system. This was a problem that had been known to exist for some time. Such losses would not have necessarily been reported to the APHIS inspectors.

Despite repeated violations of the Animal Welfare Act and failure to pass APHIS inspections, APHIS still took no action against the university for several years. A citizens' group, Californians for Responsible Research, finally brought suit against APHIS to force action. Shortly thereafter, APHIS filed a count with 42 violations of the Animal Welfare Act against Berkeley. This has led to a \$12,000 fine of which they will actually only pay \$2,000.

I think there are two very specific ways in which the present legislation can help improve the situation on APHIS inspections. The first of these is that I believe it will be difficult to hide a lack of inspections or to hide serious violations of the Animal Welfare Act when a responsible member of the local humane community is on the animal care committee. We think that is a critical provision, and it has been included with NIH's revision. That needs to be an outside person.

We are also concerned that the composition of that committee be done on a percentage basis rather than an individual basis, so that the one outside person will not be swamped by large committees.

We would also recommend an additional category. We believe that the animal care technicians who are responsible on a daily basis and are the only ones with daily contact with these animals should be included in that committee.

We have another specific thing that we would like to request be added to the act, a section titled "Civil Enforcement Suits." We

would like to provide that any person may commence a civil suit on his own behalf or on behalf of any animal protected by this chapter to compel the Secretary to apply and enforce the provisions of this chapter; that the district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to order the Secretary to take any action necessary to apply and enforce the provisions of the chapter; that the court may in fact give reimbursement to the parties involved; and that the relief provided by the section shall not restrict any right to other or additional relief which any person may have under any statute or common law.

I think, as has been shown by the case in Berkeley, that there is some issue of whether citizens have standing in this case. We think this specific addition to the bill will provide that standing and an incentive for APHIS to do its job.

Some basic general comments on points within H.R. 5725 that we think are important: We think that it would be important to mandate that the animals be kept under species-specific behavior and physical requirements rather than just sort of general. The best way to deal with things such as exercise, we think, is to allow the animals to simply engage in their natural behavioral repertoires. Exercise should not be limited to dogs but should be available to all species that require it.

Proper pre- and post-operative care, we believe, is important, but we need some clear-cut objective scales—even invasiveness, if you will—rather than subjective indications of whether or not the animal might be in pain.

When I was in training and doing research at the University of Chicago, I was told by my superiors not to worry about post-operative pain relief because it was a waste of money and the animals really didn't feel pain, anyhow, and these were surgery cases I was involved in.

We think there is a very serious problem in combining the use of paralytics with anesthetics. The concern we have here is that an animal may come out of the anesthetic while it is still paralyzed.

We would like an addition specifying that the animal's central nervous system must be monitored while it is in such a situation.

We believe that the individuals on the committee must inspect all facilities at a university and not just the animal holding facility. To give you a very specific example of a problem here, at the University of Cincinnati they had two individuals, one of whom was raising cats in his basement for use in his own research program. This would not have been known. Another individual was keeping rats in a closet in his laboratory in order to avoid paying per diem charges to the central animal facility.

I want to stress the importance of the alternative information center at the National Agricultural Library. I believe it is very important that this information be readily available.

I am a member of the panel for the OTA study on alternatives. We met yesterday, and the panel is meeting today. One of the comments that has come up is that many people in the research community are not aware of the extent to which alternatives are available or the ones that are in development. So I want to emphasize the importance of this section.

My final comment is we notice one major deficiency will still exist with the passage of this legislation, and that is that at the present time, 85 percent of the animals used in research are excluded from the Animal Welfare Act. With all the good provisions in this bill, it will accomplish little if those animals are still excluded.

Thank you.

[The prepared statement of Mr. McArdle appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Dr. McArdle.

Next is Dr. Glenn Geelhoed, director of the Surgical Research Laboratory and Transplantation Division, George Washington University. He will represent the Association of American Medical Colleges.

STATEMENT OF GLENN GEELHOED, DIRECTOR, SURGICAL RESEARCH LABORATORIES AND TRANSPLANTATION DIVISION, GEORGE WASHINGTON UNIVERSITY, ON BEHALF OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Mr. GEELHOED. Thank you, Mr. Chairman and other members of the subcommittee.

My name is Glenn Geelhoed, and I am professor of surgery at George Washington University and have been for some time the director of Surgical Research Laboratories there and, in addition, carry on an active research program and membership on a number of the organizations also represented on this panel.

I am pleased today, however, to be able to represent the Association of American Medical Colleges and the National Society for Medical Research. This is the national voice for 127 of the Nation's medical schools and 400 of their teaching hospitals and over 70 of their professional and academic societies that are engaged in this biomedical research effort.

Because of that broad constituency in the organizations that comprise the largest of the biomedical research interests in the United States, we have considerable interest in H.R. 5725.

In the interest of time, Mr. Chairman, if I might be allowed to do so, I will summarize the statement and respectfully request that I submit it to you for the entirety in the hearing record.

Mr. BROWN. Without objection, the full statement will appear in the record, and we would appreciate your summarizing it.

Mr. GEELHOED. At the outset, Mr. Chairman, this group of organizations would like to recognize the enormous and vast contributions that you have made to the scientific effort during your tenure in Congress. While we realize that you and your staff have made considerable headway in improving the language of the Dole bill, we regret that we cannot offer our full support for H.R. 5725 at this time.

As has been recognized generally by each of the panelists, laboratory animals provide a very critical role in biomedical and behavioral research, and I would think scientists especially are deeply committed to the humane care and use of these animals.

I, myself, serve on several committees in both human research and animal care, and I would like to say that I do not carry out a

species chauvinism but try to use the same ethical standards in the care of each.

Scientists, too, have that vital stake in the animal care and their humane welfare, because only healthy, well fed, and well cared for animals yield valid scientific data. However, by citing very infrequent and rather severe, extreme cases, several organizations have painted a rather unfair and unrepresentative, distorted picture of what occurs in our research institutions.

Though we are especially—not equally disturbed, but especially disturbed—that there have been a few isolated instances in which there are violations of these standards and noncompliance with these existing animal care guidelines, we caution that these have been the exception and not the rule in hundreds upon hundreds of research institutions across the Nation.

As a participant in the National Institutes of Health as well, I point out in terms of Dr. Wyngaarden's examples this morning that they are very, very rare.

There are three very compelling reasons why the enactment of H.R. 5725 would be premature at this time. First, because we are not aware of any grave systematic deficiencies that exist within our laboratories regarding the treatment of animals, we feel that a comprehensive study should be conducted before enacting any restrictive animal legislation. Such a study would identify what problems, if any, exist and determine the need for and content of future legislation in this complex area.

Second, we question the wisdom of enacting H.R. 5725 until the existing regulations under APHIS are better enforced. APHIS, the Government agency charged with the enforcement of these acts, has rarely, if ever, been provided with sufficient resources to ensure full compliance with the law.

Even though Congress has endorsed our Nation's biomedical research enterprise for over four decades, generously increasing these appropriations, the animal welfare unit of APHIS, with the major responsibility of ensuring that these laboratory animals are treated humanely, ironically has remained overburdened, underfunded, and understaffed.

With only 6 of the 485 inspectors working full time in animal inspection, and the remaining inspectors devoting only 6 percent of their time to that inspection, of over 3,000 U.S. research facilities, it is clear to us that before new legislation increasing the responsibility of APHIS is enacted, that agency should be significantly strengthened with increased appropriations and direction.

Third, we believe that Congress should postpone the enactment of any animal welfare legislation until all efforts within other governmental agencies to develop and revise existing guidelines for animal care are completed. Currently, no less than three agencies are in the process of revising existing guidelines and principles in their area of authority and responsibility. We feel that it would be prudent to postpone any legislative activity in this area until all these avenues in the regulatory arena have been completed.

While we feel our arguments for not enacting H.R. 5725 at this time are sound, we have pointed out in our full statement the concerns with some of the specific provisions of H.R. 5725. To briefly summarize our major concerns, we do not support the expansion of

the roles of the Secretary and the animal committees in the conduct of research.

Some of the proposed requirements, such as the semiannual inspection of all animal research facilities and reports thereon, will be costly and extremely burdensome. The language in general seems to denigrate the time-honored and proven peer review process already in place in many institutions, and there is no language authorizing the Federal prosecution of anyone involved in laboratory breakins and destruction and theft of laboratory animals and equipment, at least as injurious to the welfare of the animals as are some of the proposed less frequent abuses.

In conclusion, the AAMC and the NSMR sincerely believe that the enactment of H.R. 5725 would be premature, unwise, and unnecessary until, first, Congress mandates a comprehensive study of the entire research animal issue; second, Congress strengthens APHIS through increased appropriations; and, third, that the animal care guidelines under revision at at least three governmental agencies are implemented and their effectiveness analyzed.

If these recommendations are fulfilled and the subcommittee still feels the need to enact further animal legislation, the AAMC and NSMR would be happy to assist you in the development of appropriate, effective language.

I appreciate the opportunity to come before you and appreciate the Chair's concerns.

At this point, I would be very happy to answer any questions should you have some.

Thank you.

[The prepared statement of Mr. Geelhoed appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, doctor. That is a very good statement.

We will have questions as soon as Dr. Randall completes his testimony.

Dr. Randall is professor of physiology, Stritch School of Medicine at Loyola University of Chicago, and is speaking on behalf of the American Physiological Society.

Dr. Randall.

STATEMENT OF WALTER C. RANDALL, PROFESSOR OF PHYSIOLOGY, STRITCH SCHOOL OF MEDICINE, LOYOLA UNIVERSITY OF CHICAGO, ON BEHALF OF THE AMERICAN PHYSIOLOGICAL SOCIETY

Mr. RANDALL. Mr. Chairman and member of the subcommittee, my name is Walter Randall and I am here to represent the American Physiological Society's views concerning H.R. 5725, the Improved Standards for Laboratory Animals Act.

Fourteen months ago, I presented the views of the society at the Senate hearing on S. 657, which is the companion bill to H.R. 5725. I am pleased to report that most of the recommendations and many of the concerns of the society expressed at that time have been incorporated now as changes in the House version of this congressional proposal to amend the laboratory animal sections of the Animal Welfare Act.

The society applauds Mr. George Brown, sponsor of H.R. 5725, for his inclusion of our recommendations and for his sensitive understanding of our concerns.

The American Physiological Society, which I recently served as national president, represents more than 6,200 physiologists who use laboratory animals in their work as researchers and teachers. Because physiology is the study of how living beings function, it is understandable that physiologists are the largest users of live animal models for research, with more than half of the total number of animals required being used in areas of cardiovascular, neurophysiological, endocrinological, and respiratory research.

The need for laboratory animals in research is crucial and will continue, inasmuch as there are no nonanimal adjunct methods available that can replace them. May I reemphasize that the spectacular advances in medicine during the last 20 years have been vitally dependent upon animal models, and this dependency will continue for the foreseeable future.

On the other hand, the subcommittee should know that there is a decline in the number of dogs, cats, and frogs used by physiologists for educational purposes. According to a society survey, only 66 percent of the departments of physiology in the Nation's colleges and universities are using those animals now for teaching, compared with 90 percent in 1979.

There is an obvious and growing use of computer and cell culture models as supplements to animal experiments in teaching. However, what must be understood is that such computer models cannot be used for much basic live animal research, and the validity of the computer models used in teaching depends entirely upon the research measurements gained from live animal experiments.

I cite this difference in the use of animals in research with the use of animals in education because it is evidence that when proven and reliable nonanimal adjunct methods are available, they are used voluntarily by responsible physiologists as a means to conserve a vital resource.

There also is conclusive evidence from Federal records that in other areas of research and teaching, the use of live animal models decreases whenever reliable adjunct methods become available.

Because of the evidence showing both a definitive trend of decrease in number of laboratory animals being used and the growing use of reliable and proven adjunct methods, the American Physiological Society questions seriously whether laboratory animals standards as provided by the Animal Welfare Act is a legislative issue or a regulatory issue.

It is the opinion of the Society that it is a regulatory issue and that the provisions for change in the act are to be initiated by the Secretary of Agriculture.

Many of the amendments proposed in H.R. 5725 already are being addressed by the regulatory bodies within the National Institutes of Health, the Public Health Service, the Office of Technology Assessment, and by the Interagency Research Animal Committee. The actions proposed by these groups very well could and should accomplish most of what is now being proposed in H.R. 5725.

What the society believes to be a primary need at this time to assure compliance with standards set for laboratory animals is for

Congress to strengthen the role and authorities of the Animal and Plant Health Inspection Service—that is, APHIS—the agency within the U.S. Department of Agriculture responsible for enforcement of the Animal Welfare Act.

For the Congress to add additional areas of responsibility for APHIS without advancing its authorities and resources, surely will lead to greater frustrations for everyone concerned with the welfare of laboratory animals. Such an action certainly will not satisfy the intent of the Congress, nor will it serve the best interests of the public, science, and animal welfare.

The judgment of the society is that the logical approach to ensuring proper care and treatment of laboratory animals lies within the regulatory framework of the Animal Welfare Act, currently the only Federal legislative authority governing the use of animals.

For this reason alone, the society has opposed other proposals that would place similar legislative authorities in other departments of the Federal Government, because such actions would lead to a divergence of Federal standards and regulations, thus creating confusion to the researchers and increasing both the institutional and Federal costs in monitoring the Nation's Biomedical Research Program.

If the Congress has conclusive evidence that the standards for laboratory animals require additional legislative restrictions, the society then would support the concept of amending the Animal Welfare Act.

The society would like to offer to the subcommittee an amendment to the Animal Welfare Act, which was proposed at the annual meeting of the membership last month and has been unanimously endorsed by the society's governing board.

The basis for this proposed amendment is the recent criminal events at more than a dozen federally supported research institutions where laboratories were trashed, equipment vandalized, research data destroyed, animals stolen. Such actions have caused the loss of untold millions of Federal dollars and a waste of incalculable numbers of scientific manhours of work.

Each of the projects which was interrupted by such actions will have to be restarted with the expense being borne by the Federal Government. It is especially ironic that these actions also double the animal usage for this research.

The society urges the Congress to add provisions to the Animal Welfare Act authorizing Federal prosecution of those persons involved either directly or indirectly in the interference with federally funded research by the destruction and/or theft of equipment, animals, or data materials, as well as the prosecution of those persons who obtain such stolen equipment, animals, or data material.

Those who are convicted of such offenses should be held liable for both punitive damages and the cost of replacing materials, data, equipment, animals, or records which may have been damaged or cannot be returned, as well as the cost for repeating the experiments that have been interrupted and invalidated.

Most federally supported research institutions are looking to Congress to provide the support needed to halt the increasing number of incidents of attack that go beyond limits of civil demonstrations. The scientific community will work closely with the Con-

gress to develop adequate provisions that would stem this unnecessary burden for the researcher and this inexcusable waste of monies the Congress appropriates for biomedical research and the loss of animal lives.

The American Physiological Society appreciates this opportunity to express its views on H.R. 5725 and the opportunity to submit to the subcommittee its recommended amendment to the Animal Welfare Act. In addition to this statement, the society also has submitted some proposed language changes for H.R. 5725.

It would be my pleasure to respond to the members of the subcommittee who may have questions.

Thank you very much.

[The attachment follows:]



THE AMERICAN PHYSIOLOGICAL SOCIETY

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September 19, 1984

Subcommittee on Department Operations,
Research, and Foreign Agriculture
Representative George E. Brown, Chairman
U.S. House of Representatives
Washington, DC 20515

Re: HR. 5725, The "Improved Standards for Laboratory Animals Act."

The following recommendations are supplement to the American Physiological Society testimony on HR. 5725.

(1.) Exercise for dogs (Page 4, line 4)

Recommendation: Delete the sentence "(C) exercise for dogs" and add the word "exercise" in the preceding paragraph (lines 1-3) so it would read: "(B) provisions for exercise, separation by species, or other special provisions where the Secretary finds that such separation is provisions are necessary for humane handling of species;"

Rationale: Exercise should not be limited to dogs.

(2.) Prohibition on Interference with Protocols (Page 4, lines 8-15).

The Animal Welfare Act now states that "Nothing in this Act shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to design, outlines, guidelines or performance of actual research or experimentation by a research facility as determined by such research facility;...." Added to this statement (lines 11-15) is the sentence that: "The Secretary shall promulgate standards for research facilities, including requirements for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized."

Recommendation: The current language in this section of the Animal Welfare Act be left unchanged and sentence in lines 11-15 should be deleted.

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Rationale: The prohibition of interference by the Secretary or any other governmental department regarding the design, outlines, guidelines, or experimentation by a research facility is of paramount importance to continued good research. For any governmental agency to determine research methodologies, experimental design or standards for research facilities would destroy the peer review system which has proven to be the most effective tool to validate proposed research and to weed out frivolous research proposals.

This prohibition against governmental interferences with research is weakened by adding to this section a charge to the Secretary to promulgate standards for research facilities. Standards for animal care and treatment are provided for in the previous section of the Animal Welfare Act along with the authority for the Secretary to promulgate such standards. To again give the authority to the Secretary in this section of the bill is both repetitious and unnecessary and is a serious concern to the scientific community.

(3.) Animal Research Committee (Pages 6-10).

The Society has six recommendations for change in this section. They are:

Recommendation I: The committee's name (page 6, line 11) should be "Institutional Animal Care Committee."

Rationale: This committee is not charged with animal research, but rather it is a committee charged with assuring proper care and treatment of research animals.

Recommendation II: All members of the committee should be charged with being responsible for the "welfare of the animal subjects" and a sentence should be inserted (page 6, line 11) saying: "research facility. All members of the committee shall be responsible for the welfare of the animal subjects. Of the members of the committee--".

The definition of the non-affiliated member of the committee (Page 6, lines 21-24) should be broadened to read: "(ii) at least one member shall have no association with such facility and shall be responsible for the public's interest; representing community concerns regarding the welfare of animal subjects; and".

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Rationale: All members of the committee should be charged with having concern for the welfare of the animal subjects, not just the non-affiliated members. Furthermore, the non-affiliated members should represent all of the public's interests which in some cases would include more than the animals, such as the environment, toxic waste, etc.

Recommendation III: The inspection of research facilities (Page 7, line 7) should be "at least annually" rather than "semi-annually."

Rationale: At large universities and major research facilities, semiannual inspection requirements very well could amount to engaging a full-time committee working year around inspecting the various animal sites at the principal locations as well as the satellite facilities.

Recommendation IV: The reports citing violations of standards (Page 7, lines 22-23) should be changed to read: "deviations of research practices from those practices originally approved proposals that would adversely affect animal welfare;".

Rationale: Reports of violation of standards should be based on approved practices rather than proposals.

Recommendation V: The inspection results (Page 8, lines 15-16) should be a required review for Department of Agriculture inspectors. Suggested language: "(D) The inspection results shall be required by available to Department of Agriculture inspectors for review during inspections."

Rationale: The Society has found that some Department of Agriculture inspectors do not always review committee inspection reports.

Recommendation VI: The provision for suspension or revocation of Federal support (Page 10, lines 9-10) should be changed to read: "applicable standards, and the opportunity to make the necessary corrections, that agency shall suspend or revoke Federal support for..."

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Rationale: Before any suspension or revocation of Federal support, the research facility should be given due notification and a reasonable time to correct the deficiencies. Unfortunately, this has not always been the case in some previous instances of suspension or revocation of such support.

(4.) Proposed Amendment to the Animal Welfare Act.

Recommendation: Adding to the Section entitled "Findings" and preceding the section entitled "Effective Date", the following amendments are offered:

Findings (Page 2).

The Congress further finds that the welfare of animals as well as productive use of Federal research funds require regulation to prevent unauthorized possession, alteration, destruction or transporting of research records, test data, research materials, equipment and/or research animals.

Amendment (Page 12).

SEC. 28(a) It shall be unlawful for any person--

(1.) to break and enter into any Federally supported research facility with intent to destroy, alter, duplicate or obtain unauthorized possession of records, data, materials, equipment or animals.

(2.) by theft or deception knowingly to obtain control which is unauthorized or to exert control which is unauthorized over records, data, material, equipment or animals of any research facility for the purpose of depriving the rightful owner or research facility of the records, material, data, equipment or animals or for the purpose of using, concealing, abandoning or destroying such records, material, data, equipment or animals.

(3.) to possess or use records, material, data, equipment or animals or in any way to copy or reproduce records or data of a research facility knowing or reasonably believing such records, materials, data, equipment or animals to have been obtained by theft or deception or without authorization of the research facility.

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(b) Any person who violates any provision of this section shall be fined not more than \$5,000 or imprisoned for not more than one year, or both, for each such violation, and the United States District Court or the United States Magistrate, as the case may be, shall determine the reasonable cost of replacing materials, data, equipment or animals, and records which may have been damaged or cannot be returned and the reasonable cost of repeating any experimentation which may have been interrupted or invalidated in consequence of a violation of this section; and any persons convicted of such violation shall be ordered jointly and severally to make restitution to the research facility in the full amount of the reasonable cost so determined.

The American Physiological Society appreciates the opportunity to provide these supplemental recommendations for change in the language of HR. 5725.

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Mr. BROWN. Thank you very much, Dr. Randall.

I just want to express my own appreciation for the excellent analysis that you and the society have made of this legislation and your recommendations for changes and amendments. You can be sure that we will give very careful attention to those and will try to include those recommendations wherever possible.

I would like to say to all of the panelists that your testimony has been excellent. It has been directly to the point; it has been restrained; and we appreciate the contribution it makes.

In view of the fact that several of you have said such complimentary things about me, I have difficulty in finding any criticism of your statements.

Before I turn to Mr. Volkmer for questions, I want to place into the record some statements that the subcommittee has received from Our Animal WARDS of Washington, DC; Ms. Linda Huber of Piedmont, CA; and Leon C. Hirsch, president of United States Surgical Steel Corp., concerning this proposed legislation.

[The prepared statements of Our Animal WARDS, Ms. Huber, and Mr. Hirsch appear at the conclusion of the hearing.]

Mr. BROWN. Mr. Volkmer, do you have any questions that you would like to propound?

Mr. VOLKMER. I would just like to ask Dr. McArdle if he has a number that he can give us, say, within the past year of research institutions, whether federally or privately funded or what, which have caused unnecessary pain to animals or abused animals or not treated them properly.

Mr. McARDLE. To give you a specific number as to how many of them exist where they have had problems?

Mr. VOLKMER. As I understand it, we have approximately 3,000 institutions that are conducting the research, and I am just wondering, how many institutions are we talking about that are abusing the animals and are maltreating them or causing them unnecessary pain?

Mr. McARDLE. Under the present system, that question cannot be answered because the system is closed.

Mr. VOLKMER. Well, then are we going on the assumption that the research institutions are doing this and, therefore, we have to make a correction?

Mr. McARDLE. There have been specific instances, but I cannot give you the complete number because the complete number is an unknown figure. The fact that any exist at all, particularly ones such as the University of California at Berkeley, where the entire campus was in violation, I think that is the critical point to be made. If something that large can exist for that long a period of time, there is no way to know how many smaller ones. This is specifically the reason we want an outside person on the animal care committee, so we can find out whether or not the institutions are in fact causing problems with animals.

If they are not, there should be no problem. If they are, we will finally find out.

Mr. VOLKMER. Is it possible that a study could be made, at least in the Federal funding area, by authority to the agencies directly involved in the funding; or to give APHIS the authority or funds to investigate and find out how widespread this is?

Mr. McARDLE. Certainly, APHIS should have more funds. I think everyone here would agree with that.

Mr. VOLKMER. I am one of those who has always gone on the adage that if it isn't broken, don't fix it. I am not quite convinced yet that we need to impose restrictions unless something is really necessary. I hate to see biomedical and other types of research impeded in any way.

Mr. McARDLE. I would ask you to read the report I submitted as an appendix to my testimony.

Mr. VOLKMER. I will read it. I haven't had time yes, but I will read it.

I have no further questions, Mr. Chairman.

Mr. BROWN. Thank you, Mr. Volkmer.

Let me explore one area here. Several of you have indicated—Dr. Van Hoosier particularly and Dr. Geelhoed—that we have several ongoing efforts to improve the operation of the present system, and it is a little premature to make changes without the benefit of knowing how these present efforts are going.

I think that is a valid point, but I would raise this question with you. We do have some studies already in existence—the General Accounting Office report—and we have a rather extensive study that you referred to, Dr. McArdle, that the OTA is carrying on. It will not be ready for probably a few months yet, but it may be ready in a reasonably short period of time.

Would it be your opinion, Dr. Van Hoosier and Dr. Geelhoed, that if we could get a sufficient number of authoritative and reli-

able studies that indicate that corrections or modifications of the present law are necessary, that you would be supportive of making any changes that would be recommended by them?

In other words, you are not just dragging your feet here. You would be prepared to move at some point if it appeared that there was an appropriate basis on which to do something?

Mr. VAN HOOSIER. Well, certainly I have no insight to the GAO report to which you refer, Mr. Chairman.

I would point out what might be an appropriate analogy with the human subjects experience, where there was conflicting oversight by both the FDA as well as NIH. This really does create a lot of confusion in the ranks in the field, and I would certainly hope we would learn from that lesson and not make the same mistake as we proceed on the protection of animal research subjects.

Certainly there are inconsistencies, although we recognize that the law supersedes policies and guidelines. For example, in the current Animal Welfare Act, there are differences in terms of cage sizes for rabbits with the NIH guide, and people will think they are in compliance with the NIH policy and yet have a citation by a USDA inspector because of inadequate cage size. The differences are a matter of a few inches rather than anything of any substantial nature, more of a technical nature.

I know of one institution which really had to expend tens of thousands of dollars for this technical aspect—just an illustration of how discrepancies can generate a lot of expenditure of funds that may not be the best use and really help the animal on the bottom line, which is really what we want to do.

Mr. BROWN. Dr. Geelhoed.

Mr. GEELHOED. I would add that the scientific community is used to waiting for judgments until a good deal of evidence is in and avoids generalization from anecdotal evidence.

From the studies that are now under way—OTA's particularly—we are awaiting that evidence in some series. On the basis of those incidental reports that are usually quite well publicized by virtue of their very existence, pointing out that they are violations of the regulations, we are underwhelmed with a number of those, and looking at those as statements that should be generalized, I would say at the present time, I have listened carefully to such series as have been looked over by the oversights from NIH and have found those to be such vanishingly rare examples as to prove the rule rather than to point out the need for a further investigative body.

Mr. BROWN. You did use the term "underwhelmed" there, didn't you?

Mr. GEELHOED. That is correct.

Mr. BROWN. I wanted to be sure I understood that.

I would like to take this occasion to acknowledge the value of several of the suggestions that both of you made, Dr. Geelhoed and Dr. Van Hoosier. I think that it would be appropriate for this legislation to include a statement with regard to the importance of animal research, and I think both of you indicated that.

As long as we continue to experiment on human beings, I think it is appropriate we should indicate the need to continue animal research, and I think it is appropriate that we should also condemn violations of the law with regard to maintaining adequate safe-

guards against the sort of thing represented by the trashing of the laboratories. I don't think that the Congress would want to condone that in any way, shape, or form.

I would further state that I think we would be in pretty good agreement that we have to continue to improve the enforcement of the present law and to provide the resources necessary to do that.

So what I am trying to do here is to indicate the areas in which I think we are moving toward commonly agreed statements or goals in connection with this legislation.

Gentlemen, I could prolong this at considerable length with some additional questions, but I am so pleased with the statements that you have made, which are excellent, that I think I will refrain from any additional questions in light of the fact that we have reached the hour of noon.

Let me just say again that I very much appreciate the contributions that you have made this morning. We will continue to keep in touch with you for your help on this matter.

I will adjourn the subcommittee meeting at this time, to reconvene at 2 o'clock for the next panel.

[Whereupon, at 12:05 p.m., the subcommittee recessed, to reconvene at 2 p.m., the same day.]

AFTERNOON SESSION

Mr. BROWN. The subcommittee will come to order.

We have a very distinguished list of witnesses for this afternoon, and we have divided them up into two panels, somewhat as we did this morning. We expect that if we can keep each panel to about an hour, we will be able to proceed in good order.

Let me say again that all of the testimony so far—and I am sure that will be true this afternoon—has made a very good contribution to a balanced evaluation of the legislation before us and to the general subject of animal welfare. What we are trying to achieve in this hearing is a course which is balanced and prudent and not one which is either precipitous or fails to face up to the reality of the problems that do exist.

We also expect to have other members who will be here shortly. But in the interests of keeping us somewhere close to our schedule, I am going to proceed with the witnesses. Again, if you can keep your oral testimony somewhere close to 5 minutes, we will appreciate it. Of course, any material that you wish to submit for the record will be received. But in order to accommodate even a reasonable part of the witnesses that wanted to testify, we have to exercise some discipline here.

Our first panel is composed of Dr. Edward C. Melby, Jr., dean of the Cornell Veterinarian College, and president of the Association for Biomedical Research; Dr. F. Barbara Orlans, executive director of Scientists for Animal Welfare; Dr. Marshall Steinberg, secretary of the Society for Toxicology; Mr. Howard C. Brown, Jr., vice president of Scientific Affairs for the National Association of Life Sciences Industries; Mr. Marc Rosenberg, executive director of the National Coalition of Science and Technology; and Dr. John Seamer, member of the British Veterinary Association, representing Humane Information Services.

They indicate that all of you have a distinguished background in this field, and we are grateful for your appearance here.

You may begin, Dr. Melby, if you will.

STATEMENT OF EDWARD C. MELBY, JR., DEAN, CORNELL VETERINARIAN COLLEGE, AND PRESIDENT, ASSOCIATION FOR BIOMEDICAL RESEARCH

Mr. MELBY. Thank you, Mr. Chairman.

I am Dr. Edward C. Melby, Jr. I am dean of the College of Veterinary Medicine at Cornell University, and currently the president of the Association for Biomedical Research. The association represents some 200 institutions and companies around the country who are dependent upon the use of animal models in biomedical research and testing.

I want to thank you for allowing me the opportunity to appear before you today to discuss H.R. 5725, the Improved Standards for Laboratory Animals Act.

The bill proposes to amend the Animal Welfare Act. Let me start by saying it is the opinion of many within the scientific community that if improvements are required regarding the care and treatment of laboratory animals, then amending the current Federal statutory authorities, the Animal Welfare Act which is responsible for inspection of research facilities, is the appropriate vehicle, rather than promulgating new regulations within another Federal agency.

Thus, we agree completely with the general approach taken by the bill.

Having said that, however, H.R. 5725 makes two major assumptions by its very existence with which we must disagree. The first is that the overall care and treatment of laboratory animals in this country is inadequate and that the APHIS, Animal and Plant Health Inspection Service, within the USDA is equipped to implement additional requirements as outlined in H.R. 5725. To say that all research facilities meet the highest standards and to say that all animals in research are treated humanely and only used when necessary would be to imply that this is a perfect system which, of course, it is not.

On the other hand, the extent to which there are problems regarding the use of animals in research is still unknown. We cannot overlook the fact that at the present time there are no current reliable data regarding the use of animals in research. It is our hope that study legislation, which was authored by Mr. Madigan in the House and subsequently passed as part of the NIH reauthorization legislation, H.R. 2350, and introduced by Senators Hatch and Kennedy as an amendment to the Senate NIH reauthorization legislation, S. 773, which is still pending, will be enacted into law.

Within 18 months of that enactment, we would finally have accurate data regarding the care and use of laboratory animals in biomedical research. Until that time, it truly is difficult to assess the current conditions surrounding the use of animals in research and thus be assured that legislation to be enacted would accurately address deficiencies so identified.

Let me stress that the research community is not opposed to, and indeed supports, inspection of its research facilities. Unfortunately, the current Federal authority does not have the financial resources which are really necessary to ensure a quality inspection program with all inspectors throughout the country well informed and well trained. As a result, the APHIS inspection program is often found to be inconsistent and lacking in uniformity. Yet, H.R. 5725 proposes to expand APHIS's responsibility even though there is no authorization for appropriations to allow that agency to do so.

There are also several broad concerns with the legislation. They include the following: Because of the nonspecificity of some of the language in H.R. 5725, it is implied that the Secretary of Agriculture has the authority to interfere with the actual research performance, which goes beyond the purview of the current Animal Welfare Act. While we believe that APHIS responsibilities should include reviewing the care and treatment of laboratory animals, to allow the agency to get involved with research design seriously threatens the research community's ability to pursue scientific knowledge. By providing the Secretary of Agriculture with this authority, we are assuming that all USDA inspectors do possess a broad-based knowledge of the vast types of research being conducted in this country and enough expertise to assess the quality or necessity of this research.

The potential pitfalls of this language are, in our opinion, obvious. I will address this issue in greater detail in a moment.

The Association for Biomedical Research supports wholeheartedly an active animal research committee within each licensed research facility. Further, the association does not impose, and indeed supports, representation on that animal research committee of an outside member.

However, we strongly oppose the definition of an outside member in H.R. 5725 as, "one who represents community concerns regarding the welfare of animal subjects." This definition assumes that no one else on the committee is concerned with animal welfare.

Additionally, it would be impossible to determine the extent to which someone is aware of a specific community's concern regarding animal welfare.

Perhaps more importantly, the outside member should have some understanding of the scientific process as well as some understanding of the ethical considerations of using animals in research.

The association supports the language in the Walgren amendment, also part of H.R. 2350, the NIH reauthorization legislation, which defines the outside member as having no affiliation with the research facility and who is appointed by the chief executive officer of that organization.

I am submitting for the record, as an addendum, a more detailed discussion of the technical comments regarding the specifics of the language. However, I would like to take the remainder of my time to discuss some of our general concerns with H.R. 5725 and also to discuss these concerns within the larger context of the growing movement in this country which is, in our opinion, intent upon discontinuing the use of animals in research.

We recognize the tremendous pressure under which Congress has been placed regarding the use of animals in research. However, we

must not lose sight of the fact that virtually every major advance made in medicine during this century has been directly derived from animal research. Nowhere in H.R. 5725 is there mention of the importance of animal research in improving the quality of life of both humans and animals. There is no question that in certain toxicity testing and other research procedures, nonanimal methodologies are scientifically sound, especially in prescreening techniques. Yet, as I am sure you are aware, ultimately, testing must take place in animals if we are to ensure consumer safety. The research community will continue as part of the scientific process to develop additional nonanimal or adjunct techniques. But to lead the public to believe that science is anywhere near replacing the whole animal in basic or biomedical research is to misinform the public. The outcome should seriously impede the progress of science.

The Association for Biomedical Research supports not only humane and responsible use of animals in research and testing, and as such is willing and anxious to work with this committee and other Members of the Congress to achieve these goals. The major question which must be taken by this committee and other decisionmakers is whether there are problems with the current Animal Welfare Act or with the enforcement of this act.

As I mentioned earlier, APHIS has been chronically underfunded. This association and other scientific groups testify before the House and Senate Agriculture Appropriations Committees each year to increase APHIS's budget to ensure a quality inspection program. Earlier today, Dr. McArdle testified today about this concern as well.

Yet, additional appropriations have not been forthcoming. Recognizing fiscal realities in an effort to assist in the improvement of the inspection program, the Association for Biomedical Research would like to offer the following assistance to APHIS for this committee's consideration.

We will, in cooperation with ABR member institutions, provide a training program for all USDA/APHIS inspectors. This training program will include a curriculum developed in cooperation with the American Association for Laboratory Animal Science to insure that all APHIS inspectors have the same training regarding animal welfare. The cost of this undertaking will be underwritten by institutions which have a commitment to quality laboratory animal programs and who believe inspectors should be up to date and well informed regarding the speciality area of laboratory animal research.

We would like to suggest that we begin with a pilot program, training perhaps 50 inspectors initially and allowing APHIS the opportunity to assess the effectiveness of such a program. If the training program is considered effective and worthwhile, we will institute it on a regional basis to make sure that all APHIS inspectors have the opportunity to receive the same training. In this manner perhaps we can improve the quality of inspection at no cost to the Federal Government.

Second, we would like to request that this subcommittee and others within the Congress assist the scientific community and animal welfare groups in insuring that the APHIS budget is in-

creased to a degree which will allow it to implement more effective enforcement.

At this point, the question really remains, do we need additional legislation to amend the Animal Welfare Act or do we simply need to improve the enforcement program? New information, which should arise from the study authored by Representative Madigan, will assist in making this determination.

We also encourage the committee to closely review the activities of the National Institutes of Health, which is reviving its Public Health Service policies on the use of animals in research to insure complementary rather than contradictory or duplicative requirements.

In conclusion, I would like to emphasize that this association and its constituents stand ready to assist this committee in any way possible to insure the highest quality care and treatment of laboratory animals in the continuation of animal research to improve the health of this Nation.

We wish to thank you, Mr. Chairman, for your continuing understanding and interest and the leadership you have taken to resolve these very difficult issues. Thank you.

Mr. BROWN. Thank you very much, Dr. Melby. We particularly appreciate the offer that you have made to assist with the improvement of the training of the inspectors. I think that is an extremely constructive offer, and I hope we will be able to work out something on that.

Mr. MELBY. Fine.

Mr. BROWN. Our next witness is Dr. Orlans, executive director of the Scientists for Animal Welfare.

Dr. Orlans.

STATEMENT OF F. BARBARA ORLANS, EXECUTIVE DIRECTOR, SCIENTISTS CENTER FOR ANIMAL WELFARE

Ms. ORLANS. Mr. Chairman, members of the subcommittee, I am Barbara Orlans, executive director of the Scientists Center for Animal Welfare.

I speak on behalf of the organization's board of trustees in support of H.R. 5725. The Scientists Center for Animal Welfare is an organization of scientists concerned about the humane treatment of animals used in experimentation. We recognize the importance of the use of animals in biomedical research, and we believe that this effort should be adequately supported by Congress.

We were founded in 1979, and the center is an educational non-profit organization based in Washington, DC. We are currently conducting a series of regional workshops on how to run effective animal care and use committees, also known as animal research committees. The first of this series was held at Johns Hopkins University last May, and other, similar workshops are being held later this year in conjunction with other leading universities.

Over 2,000 copies of the Scientists Center's newsletter are distributed each quarter to individual and institutional members and to libraries.

There is an approximately equal representation of Ph.D.'s, D.V.M.'s, and M.D.'s on the nine-member board. Dr. Dodds, the

chief of hematology at New York State Department of Health in Albany, is currently the president. I am a Ph.D. physiologist, member of the American Society of Pharmacology and Experimental Therapeutics, author of a book on animal care, and founding president of the Scientists Center for Animal Welfare.

We believe that H.R. 5725 is a good bill. It represents a reasonable balance between the protection of animals and the needs of legitimate research. It will not impede responsible research, but it will strengthen the Animal Welfare Act in needed areas.

In my testimony I am going to just give a very brief outline of a couple of points that we want to highlight and a more detailed testimony will be submitted with your concurrence for the record.

I want to discuss two aspects, the animal research committees and the training of investigators, two provisions, important provisions, of the bill.

Some institutions have established highly effective animal research committees, but many others have given only lipservice to Federal requirements on these matters. Unfortunately, a number of these committees function very poorly, are only paper committees and exist in name alone. The recent NIH site visit study indicated the weaknesses of these committees in many cases.

What is needed is a strong stimulus to improve the effectiveness of these committees. This bill would provide such a stimulus. Particularly important are the review practices involving pain to un-anesthetized animals and the review to be conducted by these committees of the condition of the animals.

Animal welfare review performed by animal research committees has a number of unique and invaluable features not found in any other levels of review. Unlike USDA inspectors or NIH review committees, these local committees are on the spot, they can take quick, immediate action and respond quickly to any known deficiencies. They know the people involved, and I think that very often, local peer pressure from an animal research committee is more effective than remote oversight.

Experience of many research facilities has shown that these committees can function effectively with minimum delay for the investigator and do not constitute an administrative burden. Evidence of this was presented at the Scientists Center's May workshop, 1984. This was held at Johns Hopkins University as previously mentioned.

Regarding community members, already a number of institutions have appointed community representatives. These include the University of California, San Francisco; the Massachusetts General Hospital; Tufts; the University of Southern California, among others.

Such committees tend to be among the most successful of currently operating committees. To our knowledge, a number of others are in the process of appointing outside community members.

It is important that community members partake in the decision-making process of determining the standards of laboratory animal use. When Federal dollars are involved, then public accountability is a must. Not only the scientists themselves, but also the general public, must be assured that proper humane standards are maintained. Having a community member broadens the committee's

representation, helps avoid conflict of interest, and also encourages dialog between the scientists and the public to understand each other's viewpoint.

Regarding training, adequate training courses do not currently exist. Investigators are particularly poorly served in comparison with technicians. Many investigators are conducting highly invasive, pain-inflicting experiments on animals, with never having taken a course on humane techniques at any point in their education. Some investigators don't even know that the Animal Welfare Act exists or that NIH has established guidelines and policies. It is a situation that defies common sense.

Two types of courses are needed: first, the practical nuts and bolts of humane techniques, and second, another covering philosophical and ethical aspects. According to a survey that the Scientists Center for Animal Welfare did recently, there are some 21 U.S. colleges that offer courses on ethics and animals. Considering the fact that there are many hundreds of colleges in the United States that are training scientists, biomedical scientists, and only 21 offer any instruction at all on humane attitudes, it can be seen that there is much room for improvement.

In addition, there are almost no separate courses on humane techniques that are available for investigators. Some are available for technicians that are given very ably by the American Association for Laboratory Animal Science.

Some Federal initiative, backed up by Federal dollars, needs to be given in this important area of investigator and other personnel training. H.R. 5725 provides a needed start in this important matter. We do think that annual training sessions may be too frequent at this stage and that this provision may be premature, because there is such a lack of courses available.

In summary, the board of trustees of the Scientists Center for Animal Welfare believes that this bill is a necessary piece of legislation worthy of support. Its passage would provide the needed force to ensure that research institutions fulfill their responsibilities for animal welfare. It is of prime importance that federally funded animal experiments are conducted with utmost care and regard for the animals. Thank you.

[The prepared statement of Ms. Orlans appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Dr. Orlans.

Our next panelist is Dr. Marshall Steinberg, secretary of the Society for Toxicology.

STATEMENT OF MARSHALL STEINBERG, SECRETARY, SOCIETY FOR TOXICOLOGY

Mr. STEINBERG. Mr. Chairman, my name is Dr. Marshall Steinberg. I am the secretary of the Society for Toxicology. Mr. Chairman, in the interest of time I would like to summarize my statement, but I ask that it be included in the record in its entirety.

Mr. BROWN. The statement will be included in its entirety.

Mr. STEINBERG. The Society of Toxicology is a nonprofit scientific organization dedicated to the furtherance of the science of toxicology. We are not affiliated with any trade organization, and our

membership is drawn internationally from academia, government, and industry, with the largest single bloc of membership being from academia.

The Society of Toxicology supports the principles of H.R. 5725 in ensuring the health and well-being of laboratory animals. We are pleased to note that H.R. 5725 is an amendment to the existing Animal Welfare Act rather than a new act.

Annual training sessions for all personnel involved with animal care and use in the research facility are also supported.

However, I would like to make a few points. In toxicology, scientific investigations range from the use of whole-animal models to in vitro subcellular techniques. The research conducted includes work done by educational institutions, the government, chemical and drug manufacturers, and contract laboratories. The gamut of toxicological research ranges from studies of basic mechanisms of action to testing to meet regulatory requirements.

While in vitro techniques have proven to be invaluable tools in basic research, they have not been the replacement that people thought they would be for safety evaluation studies using whole animals. They have, however, proven to be an extremely valuable addition to the armamentarium of tests that are conducted for safety evaluation of agrichemicals or drugs.

We believe that there is a need for clarity of definition with respect to distress in an experimental animal, as used in the proposed legislation. Safety studies are required by regulation to produce a toxic effect or a high dose. It is usually the improperly designed study where the high dose does not produce an effect. Technically, a well-designed study could be in conflict with the law and/or could require considerable documentation to accomplish that which is scientifically valid.

It is suggested that, rather than the Secretary of Agriculture developing standards, there be provision for guidelines and each facility be required to develop standard operating procedures to ensure that animal pain and distress are minimized consistent with the relevant scientific needs of the experimental procedures. These SOP's would then be subject to good laboratory practices, where applicable.

It is felt that the amendment tends to make the animal research committee an extension of Government instead of an integral oversight group of the institution, as in the case of the quality assurance unit. People providing input to the committee should see their role as one of bettering the handling and treatment of animals rather than reporting on the activities of the institution.

We also believe that the requirement for separation of species needs a provision for exemption, and the requirement for exercise is an issue requiring the professional judgment of the attending veterinarian. Some research, such as inhalation studies, must by necessity have several species in separate cages but in the same chambers. A review of the literature would indicate that there is no difference in the physical parameters for a laboratory-bred dog that is penned under the provisions of the National Research Council guidelines and the same animal that is exercised according to a predetermined schedule.

As indicated in the amendment, the members of the committee are required to possess sufficient ability to assess the various aspects of animal care. It is suggested that the committee possess sufficient ability for it to carry out its mandate. This would permit the assignment of various specialists to the committee and allow greater flexibility, particularly with respect to the outside member. It is conceivable that the surrounding community may not be able to provide an individual with the knowledge in animal care, treatment, and practices in experimental research.

There is no dichotomy between animal welfare and the development of the science of toxicology, and it is noted that H.R. 5725 does recognize the need to conduct research and that the use of animals may be central to that research. The Society of Toxicology has animal welfare and legislative liaison and assistance committees that would be pleased to work with the committee members and the staff in providing scientific input that may be indicated.

Mr. Chairman, thank you for the opportunity to present these viewpoints, and I would be pleased to answer any questions.

[The prepared statement of Mr. Steinberg appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Dr. Steinberg.

Our next panelist is Mr. Howard C. Brown, Jr., vice president of scientific affairs for the National Association of Life Sciences Industries.

Mr. Brown.

STATEMENT OF HOWARD C. BROWN, JR., VICE PRESIDENT, SCIENTIFIC AFFAIRS, NATIONAL ASSOCIATION OF LIFE SCIENCES INDUSTRIES, INC., ACCOMPANIED BY ANDREW S. TEGERIS, M.D., VICE PRESIDENT, SCIENTIFIC AFFAIRS, NATIONAL ASSOCIATION OF LIFE SCIENCES INDUSTRIES, INC., PRESIDENT, PHARMACOPATHICS RESEARCH LABORATORIES

Mr. HOWARD BROWN. Thank you, Mr. Chairman. My name is Howard Brown. I am the vice president and executive director of the National Association of Life Sciences Industries, which we call NALSI, for short. NALSI is a nonprofit trade association comprised of independent toxicology testing laboratories, usually referred to as the "contract laboratories."

Mr. Chairman, I am accompanied today by a distinguished physician and scientist, Dr. Andrew Tegeris, at the end of the table, who is vice president of scientific affairs for NALSI, and who also is president of Pharmacopathics Research Laboratories of Laurel, MD.

With your permission, Mr. Chairman, I would like to submit the full text of our statement for the record and summarize the salient points in the interest of time.

Mr. BROWN. Without objection, that will be the order.

Mr. HOWARD BROWN. A primary objective of H.R. 5725 is to minimize pain and distress in laboratory animals used in research and testing. The chairman may recall that NALSI's strict code of ethics which evolved as a result of the chairman's guidance requires that each of its members comply with all government regulations—State, Federal, and local—on laboratory animal care and use. A

mechanism that the bill would institute to achieve its objectives is the requirement that each facility establish an animal research committee; one member of that committee would have no association with the facility and would represent community concerns.

NALSI believes that this mechanism involves risks to the private commercial laboratory and risks to the nonassociated community member as well. In a contract laboratory the proprietary data or trade secrets that may be involved in the product or device being tested may be the property of the product sponsor, the contract laboratory, or both. We assume that individuals serving on the committee would offer high personal integrity and scientific competence. The fact is, however, that the financial worth of the proprietary data involved in the studies will be substantially greater than the personal resources of most individuals.

The sanctions which the bill provides against the unauthorized release or use of trade secrets—namely, fines and imprisonment and the recovery of actual and consequential damages—certainly represent powerful deterrents. Nevertheless the financial consequences to the owner of the product or device resulting from its compromise may dictate that the product not be tested under circumstances in which a substantial proprietary investment is exposed to individuals who have no contractual responsibility for its protection.

In brief, the sanctions provided in the bill are deterrents, but they cannot assure recovery of the loss of a substantial investment in a new health product.

The nonassociated community member also is placed in an awkward position. The individual does not enjoy the rewards or benefits of employment, but would be exposed to the same risks that attend laboratory scientists and technicians. It is the very nature of toxicity testing that toxic or carcinogenic effects of products or devices be observed. Superimposed on these possible risks are the sanctions of fines and imprisonment for the release of confidential data.

We are concerned that qualified candidates may not find service on this committee particularly attractive in view of these kinds of exposures.

If the provision in the bill for a nonassociated community member of the animal research committee is to be retained, we recommend further study of the anomalies we have briefly described. NALSI believes that such a provision is not necessary to the achievement of the bill's objectives. In addition to the Department of Agriculture inspectors, for whom we have great respect, there are four other Government entities which have statutory responsibilities for the proper care and use of laboratory animals. These entities are the National Institutes of Health, the Public Health Service, the Food and Drug Administration, and the Environmental Protection Agency. They, too, employ highly competent personnel.

We believe that these resources are more than adequate to assure achievement of the bill's objectives.

Mr. Chairman, in the interest of the limitations of the committee's time, we have focused on one aspect of the bill that we consider potentially troublesome. Time permitting, we would have liked

to have underscored with approval other provisions of the bill which are in it.

This completes our oral summary. Dr. Tegeris and I would be pleased to respond to questions from the committee or from our colleagues on the panel. Thank you.

[The prepared statement of Mr. Brown appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Mr. Brown. You have raised an important question which, as you know, we have been concerned with, and we will continue to give that very careful study.

The next panelist is Mr. Marc Rosenberg, executive director of the National Coalition of Science and Technology.

**STATEMENT OF MARC H. ROSENBERG, EXECUTIVE DIRECTOR,
NATIONAL COALITION FOR SCIENCE AND TECHNOLOGY**

Mr. ROSENBERG. Mr. Chairman, my name is Marc Rosenberg. I am the executive director of the National Coalition for Science and Technology. Our membership includes approximately 1,000 research scientists, educators, business people, and engineers. We also count a number of corporations and professional societies among our members.

We would like to submit our prepared statement for the record and present a very brief summary of it this afternoon.

Mr. BROWN. Without objection, so ordered.

Mr. ROSENBERG. The subject of animal welfare is of keen interest to many of the individuals and organizations we represent. It is a controversial topic, as you are well aware, and we commend you for holding today's hearing. The National Coalition for Science and Technology believes it is useful to have a public forum for a continuation of the dialog between those who do animal research and those who are involved in the animal welfare movement.

For several reasons, however, the national coalition does not support passage of H.R. 5725 or any other animal welfare legislation in these closing days of the 98th Congress. As you know, there is a comprehensive study presently being conducted by the Office of Technology Assessment, and they are expected to report their findings in 1985. The coalition believes the Congress should have the benefit of that detailed study before any new legislation is enacted.

Moreover, this is a very difficult subject that will require a broad consensus, which may take longer than the few weeks remaining in Congress in order to be obtained.

In fact, earlier this year the National Coalition for Science and Technology itself sponsored a national forum on the use of animals in research and testing. After a full day of presentations in workshops, there emerged a consensus that more could be done to reduce the duplication of animal research, to reduce the number of animals used in certain testing, and to improve dissemination of information about alternative methods of research and testing. The relative ease with which this consensus emerged leaves us optimistic about the outcome of a responsible and reasoned public dialog on this subject.

We are aware that there are many people who question whether animals in laboratories are adequately protected by the current

law. In several areas of the country, including the chairman's home State of California, concern over the care of animals used in research has jeopardized public support for certain health-related research programs.

With respect to the specifics of H.R. 5725, we would like to focus our comments on five particular provisions in the pending legislation. First, the requirement that laboratories using animals establish local review committees. We are worried that each local review committee would be left to establish its own standards and values concerning how animals should be treated. As a result, we could end up with a hodge-podge of inconsistent requirements, with a particular practice deemed acceptable at one institution and prohibited at another.

As we are talking about federally funded research or Government-mandated testing, we feel that before these local review committees are established, we should have some agreement as to what standards are to be applied.

We also believe there should be a definite and swift appeals process that would provide researchers recourse in the event that a local panel strays from the national norms.

Second, there is the provision that the members of a local review panel must agree to the protection of trade secrets and proprietary data. This provision is a marked improvement over other proposals we have seen, and we commend you for it.

Third, there is the proposal to create a voluntary national clearinghouse for information concerning animal research and alternative methods of research and testing. Such a clearinghouse would be useful, and we support it in concept.

Even if the clearinghouse is placed within the National Agricultural Library, as proposed in this legislation, it would either require a separate line item in the budget or an explicit reprogramming of funds already available for other purposes. Perhaps H.R. 5725 is not the appropriate vehicle for that sort of language, but we believe that it should be included in either authorizing or appropriating legislation.

Additionally, we feel that stronger language is needed to assure full cooperation and interaction with the National Library of Medicine and the Department of Health and Human Services.

Fourth, there is the requirement that institutions using animals for research and testing must annually provide their personnel with information and training relevant to the humane treatment of laboratory animals. As an alternative to this specific provision, we suggest accepting the inclusion of this information in continuing education or periodic recertification requirements of the principal investigators or the professional staff of the facilities.

Additionally, if such courses and training are required, then we should consider what assistance the Federal Government can provide in meeting this new obligation. If I could stray from our text at this point, we would like to underscore our concern that the ability of these institutions to provide the necessary training programs is our primary concern, and we think that some structure outside of the specific institution is probably going to be more effective.

The fifth point is that there are some specific rules set forth for surgical procedures involving animals. NCST recommends that these be removed from the legislation. Rather than setting these rules of surgical procedure in the statute, we think it would be more appropriate and pragmatic to leave the setting of standards of care to the regulatory process. Again, we are concerned by the inconsistencies that could result from leaving this up to the local review panels to grant exceptions in the absence of guidelines.

In summary, Mr. Chairman, I again stress that the National Coalition for Science and Technology applauds your efforts to promote rational dialog on this subject. We believe that today's hearing helps to pave the way for substantive legislation in this coming year, and we stand ready to help you develop legislation which would assure the public that laboratory animals are indeed being treated humanely while the Nation's researchers are permitted to make further progress in protecting and improving the health and well-being of our citizens.

[The prepared statement of Mr. Rosenberg appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Mr. Rosenberg.

Our last panelist is Dr. John Seamer, who is a Member of the British Veterinary Association, representing the Humane Information Services. And I should comment that the British have had legislation in this area for over 100 years. Their experience should be very valuable to us.

Dr. Seamer.

STATEMENT OF JOHN H. SEAMER, MEMBER, BRITISH VETERINARY ASSOCIATION, REPRESENTING HUMANE INFORMATION SERVICES OF THE UNITED STATES

Mr. SEAMER. Thank you, Mr. Chairman. My name is John Seamer, and I am appearing on behalf of the Humane Information Services of the United States. But I am the honorary secretary of the British Veterinary Association. I would like to say what an honor it is to be invited to appear before you.

You may wish first, of all, that I establish my credentials. I have spent many years in scientific research using both animals and tissue cultures. Latterly, I was responsible for the breeding and supply of animals for research and was also curator of an experimental animal house. I have written scientific papers and contributions to scientific books, and I have edited a handbook called, "Safety in the Animal House."

I am a member of the editorial board of the Journal of Laboratory Animals, and earlier I was president of both the Laboratory Animal Science Association and the British Laboratory Animal Veterinary Association.

I have served on the council and committees of the British Veterinary Association for many years and was chairman of the Animal Welfare Committee before becoming the association's honorary secretary last year.

As you say, Mr. Chairman, in Britain there has been a law controlling experiments on animals for more than 100 years. It is my opinion, and indeed I believe, that of the general opinion of British

scientists also, that this law has in no significant way restricted the advance of experimental science.

I have read the provisions of the U.S. Animal Welfare Act, as amended, and also the bill H.R. 5725. The provisions of the present U.S. legislation on animal experiments and those in the new bill are very different in detail from the law in Britain. The British law is, however, more restrictive, for it applies to all vertebrates, whereas the U.S. law, as I understand it, applies only to warm-blooded animals.

The principal welfare problem in animal experiments is animal suffering or pain. In this respect also, the protection of animals in the United States does not seem to extend as far as it does in Britain. For more than 50 years, all British animal experiments have been subject to what is known as the pain condition. The most important clause of the pain condition states: "If an animal at any time during any experiment is found to be suffering from severe pain which is likely to endure, such animal shall forthwith be painlessly killed."

Thus, regardless of the nature or purpose of the experiment, and regardless of whether or not a result has been achieved, it is the rule that any animal suffering severe pain which is likely to endure shall be killed forthwith.

I know of no great difficulties that British scientists have had with this particular condition. It is, of course, virtually impossible to define pain in such terms as "endure." Nevertheless, as I say, British biological scientists have worked with the pain clause for many years without detriment to their experiments and with benefit to the welfare of animals.

Indeed, the pain clause is not now considered to be sufficiently restrictive. The British Veterinary Association, with the support of the Committee for the Reform of Animal Experimentation and the Fund for the Replacement of Animals in Medical Research—these are two worthy animal welfare organizations in my country—the British Veterinary Association is pressing the British Government for improvements in the law relating to experimental animals. I would wish, Mr. Chairman, to submit to you evidence which can be written in, if that is your wish.

Mr. BROWN. We would be pleased to have that, and it will be made a part of the record, Dr. Seamer.

Mr. SEAMER. Thank you, sir.

With regard to pain, my association wishes that all animal experiments should be subject to the condition that any animal that is suffering severe pain or severe distress that cannot be alleviated should be killed, even if the object of the experiment has not been achieved. In this way, we propose to reduce still further the upper limit already existing on the amount of pain that animals under experiment may suffer.

As an eminent British scientist, Sir Graham Wilson, said when appearing before a U.S. congressional committee considering animal experimentation in 1965, scientific workers believe that there is a degree of pain which no human being has the right to inflict on an animal no matter what increase in knowledge might be expected to result.

It is at this point that the claims of morality overstep those of scientific inquiry. Thank you, sir.
[The attachments follow:]

Animal Experimentation in the United Kingdom

PROPOSALS SUBMITTED TO THE HOME SECRETARY
JOINTLY BY
THE BRITISH VETERINARY ASSOCIATION
THE COMMITTEE FOR THE REFORM OF
ANIMAL EXPERIMENTATION
AND
THE FUND FOR THE REPLACEMENT OF ANIMALS
IN MEDICAL EXPERIMENTS

MARCH 1983

The British Veterinary Association (BVA), the Committee for the Reform of Animal Experimentation (CRAE) and the Fund for the Replacement of Animals in Medical Experiments (FRAME) having agreed on the measures which should be included in new legislation for the control of Animal Experimentation in the United Kingdom have the honour to submit these views for the consideration of the Secretary of State.

We believe that these proposals represent an effective compromise between the welfare needs of the animals, the legitimate demands of the public for accountability and the equally legitimate requirements of medicine, science and commerce.

BRITISH VETERINARY ASSOCIATION
7 Mansfield Street, London, W1M 0AT.

COMMITTEE FOR THE REFORM OF ANIMAL EXPERIMENTATION
10 Queensferry Street, Edinburgh, EH2 4PG.

FUND FOR THE REPLACEMENT OF ANIMALS IN MEDICAL
EXPERIMENTS
5B The Poultry, Bank Place, Nottingham, NG1 2JR.

INTRODUCTION

Experiments on animals to advance biological knowledge, to improve human and animal health and welfare and for essential safety and potency tests have led, and continue to lead, to significant benefits for man and animals. Such experiments should continue provided that the new legislation safeguards the welfare of animals used in experiments by incorporating the provisions detailed below.

1. PROCEDURES AND ANIMALS

A procedure, for the purposes of the legislation, should be defined as any experimental or scientific act involving interference with or departure from the normal condition of well-being of an animal, which may cause pain, suffering, distress or lasting harm. All procedures should come within the scope of the legislation and it should be an offence to carry out a procedure without authority. There must be suitable exemption for the performance of veterinary procedures carried out in accordance with the provisions of the Veterinary Surgeons' Act of 1966 and amendments.

The legislation should apply to all non-human animals in the sub-phylum *Vertebrata* including the foetuses of animals and the embryonic or larval forms of other classes that have attained a stage of development capable of discrete existence outside the egg or maternal tract.

2. ACCEPTABLE PURPOSES

Procedures should be allowed only for one or more of the following purposes:—

- (a) The avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects in man, animal or plant. This purpose includes the production and safety testing of medicinal products and other substances, the quality control of foods, and the development of surgical techniques.
- (b) The assessment or detection of physiological conditions, including the diagnosis of pregnancy.
- (c) The prolongation of life of man, animal or plant.
- (d) The protection of the natural environment.
- (e) The breeding of animals.
- (f) The advancement of biological knowledge.
- (g) Some educational and training purposes. The use of anaesthetised animals which are not allowed to recover consciousness for the acquisition of manual skill should be permissible under strictly controlled conditions. Survival surgery for the acquisition of manual skill should be permitted only in exceptional circumstances such as training in micro-surgery. The use of recorded material for demonstration in higher education should be extended.

3. LICENSING OF PREMISES AND PLACES

All procedures under the legislation must be carried out on premises or places licensed for the purpose. The licence for the premises or places should specify the types of procedures which may be carried out. The licence should identify two or more people by name:—

- (a) The person or persons ultimately responsible for the care of the animals in the premises or places; *and*
- (b) the veterinary surgeon, either from the staff of the establishment or employed on a part-time basis, responsible for advice on animal health and welfare.

A legally enforceable Code of Practice should lay down required standards for premises, places and facilities available for the care of the animals and for the carrying out of the licensed procedures.

The Code should specify that a sufficient number of competent staff are available at all times to care for the animals, especially those that have undergone surgical interference. The Code should also specify that an animal used or intended for use in a procedure is provided with suitable and adequate accommodation, an environment, sufficient freedom of movement, and food and water appropriate to its health and well-being. The environmental conditions should be checked at least daily and the state of health of all animals in licensed premises or places should be observed sufficiently frequently and in sufficient detail to ensure their well-being in the context of the procedure. The Code of Practice should specify conditions for the transfer of animals between licence holders, or between licensed establishments during the course of, or at the end of, a procedure.

Legislation should permit the performance of procedures in open spaces and natural environments.

4. LICENSING OF PERSONS AND PROCEDURES

Licences for individuals to carry out procedures should be issued by the Secretary of State on application by the prospective licensee. The application should be counter-signed by two sponsors. The first sponsor should be the holder of a senior appointment in the biological sciences at the establishment of the applicant, who is familiar with the applicant and the facilities available. He should certify that the applicant is a suitable person to hold a licence, and that he is competent in the handling of the animals to be used in the procedures specified in the application, and is competent to perform the specified procedure or procedures and any anaesthetic or analgesic techniques to be used. The first sponsor should also certify that the procedure or procedures conform to the provisions of the legislation, with particular reference to the acceptable purpose for which the procedures are to be performed. The applicant and first sponsor may wish to consult with a non-statutory local ethical committee before forwarding the application to the second sponsor.

The second sponsor should be an independent biological scientist from another establishment whose name is listed in a register of sponsors approved by the Secretary of State. The second sponsor should certify that, in his opinion, the procedure or procedures conform to the legislative provisions, and that they are justified in the circumstances, after having considered the possibility of using alternative techniques which do not involve the use of animals. In any application involving the use of primates, the second sponsor should certify additionally that the use of primates is essential.

Strict control should be exercised over the procedures and animal species permitted on licences. When procedures are to be carried out on unanaesthetised animals, or on anaesthetised animals which are to be allowed to recover, the licence should specify such species as may be used and should define the permitted procedures.

The recipient of a first licence should be subject to the direction and supervision of an experienced licensee, irrespective of the qualifications and training of the recipient. This first licence should normally be valid for one year only, and a report from the Supervisor to the local Inspector should be submitted and considered before the licence is renewed without the supervision condition. There should be provision for the issue of licences with longer-term supervision conditions, provided that there is always an assessment of competence after the expiry of the first year.

Variations of any licence should be made either at the request of the holder, or of the Secretary of State.

Licences should be available for inspection at all reasonable times by an Inspector.

An undergraduate or postgraduate student of any biological science should be permitted to carry out procedures on licensed premises without being the holder of a licence, provided that it is under the direct supervision of and in the presence of a licence holder, and that the animal is anaesthetised throughout the procedure and is humanely killed at the end of the procedure without regaining consciousness.

5. CONDUCT OF PROCEDURES

A procedure starts when an animal is first prepared for use in that procedure, and ends when no further observations are to be made for the purpose of the procedure.

It is reasonable to allow the re-use of animals under certain conditions. It must be decided at the end of any procedure whether the animal shall be kept alive or humanely killed, provided that it shall not be kept alive if it is likely to remain in lasting pain or distress. At the end of a procedure animals which are to be kept alive must continue to be kept subject to the conditions of the procedure and must be placed under the supervision of the veterinary surgeon identified on the licence of the premises. An animal may be exempted from these conditions if, in the opinion of the veterinary surgeon, it would not suffer as a consequence of such exemption. It may be necessary for the purposes of the procedure to set non-domesticated animals free or return domesticated animals to their normal (i.e. non-experimental) environment. This should be permitted by the licence provided that the Secretary of State is satisfied that the maximum practicable care has been taken to safeguard the animal's well-being.

When an animal is not to be kept alive, it should be humanely killed without avoidable delay.

6. PAIN, ANAESTHESIA AND ANALGESIA

The problem of defining pain, suffering or distress has not been resolved satisfactorily. However, it is possible to recognise various states of discomfort, stress or pain, both in the intensity and the duration of the suffering. For example, a very brief painful stimulus such as the insertion of a sharp needle through the skin is probably inconsequential; on the other hand, the stress imposed in the restraint and immobilisation of the animal prior to the insertion of the needle may be severe. Thus it is the recognition of the response of the animal to a stimulus that should be the criterion of suffering, rather than the nature of the stimulus itself. It is possible also to recognise differences in the origin of the suffering, whether it be from wilful neglect or incompetence, whether it be incidental to or unexpected within the procedure, or whether it be a necessary component of the procedure.

The following provides a useful guide to the recognition of the various states of suffering, based on paragraph 181 of the Littlewood Report. *Discomfort* may be characterised by such negative signs as poor condition, torpor and diminished appetite or by positive signs such as avoidance. *Stress* is a condition of tension or anxiety which may be predicted or readily explained by environmental causes whether distinct from or including physical causes. *Pain* is recognisable, but not necessarily quantifiable, by positive signs such as struggling, screaming or squealing, convulsions and severe palpitations or by measurement of chemical changes within the body.

During any procedure, suitable anaesthesia, analgesia or other measures compatible with the standards of contemporary veterinary practice, and designed to alleviate pain, suffering or distress of whatever origin occurring during the procedure, should be applied at any time, unless they are more distressing for the animal than the procedure itself or unless they would conflict with the purposes of the procedure. If a procedure is likely to cause pain, suffering or distress of more than momentary duration or trivial intensity, which cannot be alleviated, prior authorisation by the Secretary of State should be obtained. Such authorisation should only be given when the procedure is judged to be of exceptional importance in meeting essential needs of man or animals.

All licences should contain provisions to ensure that any animal that is suffering *severe pain or severe distress* which cannot be alleviated should be killed even if the object of the procedure has not been achieved.

The use of curariform drugs should be prohibited, except in conjunction with anaesthesia of sufficient depth to produce loss of consciousness.

7. ACQUISITION OF ANIMALS

Animals for use in experiments should be bred for the purpose, although exceptions should be permitted for scientific reasons and in the case of farm animals. The use for experimental purposes of cats or dogs taken from the streets should never be permitted. Exceptions to the purpose breeding rule for cats and dogs should be stringently controlled: financial grounds alone should not be a sufficient reason for an exception to be made.

Animals of the species listed below which are intended for use in procedures should be obtained only from registered breeding establishments, except:—

- (a) That exemptions from this requirement may be given for specific reasons or procedures; and
- (b) that free-living varieties of the listed species may be used in a procedure where the main object of the procedure is the study of the free-living variety.

Animals of species other than those listed below should be acquired from registered establishments wherever possible. In reaching a decision to use wild animals for experimental purposes the welfare of the animals, the survival of the species and the quality of the experimental material should be taken into account: financial grounds alone should not be a sufficient reason for an exception to be made. The general source of animals intended for use in procedures which will not be acquired from registered establishments should be stated when application is made for the licence to carry out the procedure.

Listed Species

Mouse	<i>Mus musculus</i>
Rat	<i>Rattus norvegicus</i>
Guinea Pig	<i>Cavia porcellus</i>
Rabbit	<i>Oryctolagus cuniculus</i>
Dog	<i>Canis familiaris</i>
Cat	<i>Felis catus</i>
Hamster	<i>Mesocricetus auratus</i> and <i>Cricetulus griseus</i>

Other species, and particularly primates, should be added to this list as soon as there is reasonable prospect of a sufficient supply of purpose-bred animals.

8. REGISTRATION OF BREEDING AND SUPPLYING PREMISES

Control of the breeding, keeping, supply and transport of animals intended for use in procedures is essential. Establishments which breed or supply animals should be registered by the Secretary of State, and a legally enforceable Code of Practice should lay down the required standards for premises breeding and supplying animals for experimental purposes. The Code should specify the standards of premises, and the facilities required before registration is granted. The numbers and competence of staff should be specified. The certificate of registration should identify the person or persons ultimately responsible for the care of the animals in the establishment and the veterinary surgeon responsible for advice on animal health and welfare in the establishment.

9. RECORDS AND RECORDING

In order to facilitate the keeping of records of animal movement and usage, canidae, felidae, ungulates and primates intended for use in procedures, should be individually identified at the earliest practicable time after birth or after being taken into a licensed or registered establishment. The identification should be in the most permanent form available for the species and nature of the individual. Full records of the identity and origin of each member of the families listed above should be kept by all licensed or registered establishments.

Records of the movement of other species should be recorded by total number only.

The records should be in such a form as to show, as far as practicable, the origin, lifetime movement, usage in procedures and disposal of all animals, either by group or individually, as described above.

All persons licensed to carry out procedures should keep records of movements of animals intended for use in their own procedures and of the usage of animals in the procedures. Records from all licensed or registered persons should be submitted annually to the Secretary of State.

10. ANNUAL REPORT

The Secretary of State should present to Parliament, annually, a report which should include at least:

- (a) The total number of procedures carried out during the previous year.
- (b) The purposes for which the procedures were carried out.
- (c) The number and species of animals used.
- (d) The number of exemptions from the basic pain condition granted during the year.
- (e) A statement of any infringements of the legislation, and the consequences.
- (f) The subjects on which the Advisory Committee had advised during the year.

11. INSPECTORS

Inspectors should continue to be recruited from mature persons holding registered medical or veterinary qualifications.

Their statutory duties should include:

- (a) The scrutiny of applications for licences in regard to the nature and purpose of the procedures to be carried out, and the assessment of the suitability of the applicants to perform such procedures.
- (b) The unannounced periodic inspection of licensed and registered establishments and the inspection of those for which application has been made. Refusal of entry to an authorised inspector at any reasonable time should be an offence.
- (c) To advising the Secretary of State as to the exercise of their duties.

Inspectors should have absolute discretion to order the killing of any animals considered to be suffering unduly at a licensed or registered establishment.

12. ADVISORY COMMITTEE

An Advisory Committee should be established and should consist of a Chairman and twelve members, all appointed by the Secretary of State in a personal and not in a representative capacity.

The Committee should:

- (a) Keep under continuous review (i) the extent to which animals are used in procedures which may cause pain, suffering or ill-health and (ii) other matters relating to the welfare of animals used or for use in procedures.
- (b) Provide the Secretary of State with such other relevant advice and guidance as they think he requires, particularly with reference to the use of alternative techniques.
- (c) Consider particular procedures which come to their notice or are referred to them by the Secretary of State and advise whether or not, and subject to what conditions, such procedures are justified.
- (d) Advise the Secretary of State on any relevant matters which he may refer to the Committee for their opinion.

The Committee should be composed of persons qualified by their knowledge and experience to render competent advice to the Secretary of State on any or all aspects of the matters referred to in (a) to (d) above. The members should include veterinary surgeons, biological scientists, representatives of the medical profession and lay persons.

13. APPEALS

There should be an adequate statutory procedure for appeals against a decision made by the Secretary of State, concerning licences for procedures, licences for premises and places, or registrations for establishments.

14. PUBLIC EXHIBITION

Exhibition to the general public of visual recordings of procedures on living animals should be permitted where the recordings of procedures were originally made for an acceptable purpose as defined in Section 2.

Exhibition to the general public of procedures, or recordings of procedures, on living animals made specifically for exhibition, should not be permitted except:

- (a) Where the prior approval of the Secretary of State has been obtained; or
- (b) where the audience consists entirely of students or workers in the biological sciences.

15. RESTRICTION ON RIGHT TO PROSECUTION

To protect licensees or holders of certificates of registration from malicious or vexatious prosecution, a prosecution against a person licensed or registered under the legislation for an offence under the legislation should not be begun except on the instructions or with the consent of the Director of Public Prosecutions.

Proceedings should be commenced within two years of the commission of the offence or within six months of the discovery of the offence.

ILARNEWS

INSTITUTE OF LABORATORY ANIMAL RESOURCES

About the Author

After a two-year term as Chairman of the Animal Welfare Committee of the British Veterinary Association, Dr. John Seamer is now the official nominee to become Honorary Secretary of the BVA in September 1983. He has played a leading role in laboratory animal science in Britain and internationally. He has served as Council Member, Secretary, and President of the Laboratory Animal Science Association and of the British Laboratory Animals Veterinary Association and was also Scientific Member of the Governing Board of the International Council for Laboratory Animal Science. For several years he was responsible for the breeding, production, and care of experimental animals at Allington Farm, Chemical Defence Establishment, Porton, Salisbury, UK, and he has published many papers on laboratory animals and on microbiology. A member of the editorial board of *Laboratory Animals*, he has also edited the handbook *Safety in the Animal House*.



HISTORICAL BASIS OF BRITISH VETERINARY ASSOCIATION POLICY ON ANIMAL EXPERIMENTS

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INTRODUCTION

The British Veterinary Association (BVA) has a membership of some 7,000 graduate veterinarians. It is the professional association that represents the interests of all arms of the veterinary profession in Britain, whereas the legal control of the practice of veterinary medicine is vested in the Royal College of Veterinary Surgeons (RCVS). On becoming a member of the RCVS every veterinarian makes a solemn declaration and a promise that "my constant endeavour will be to ensure the welfare of animals committed to my care." All full members of the BVA are members of the RCVS. Thus, although many people and professions play a part in animal welfare in Britain, veterinarians have a particularly important role to play by virtue of their solemn promise.

The interest of British veterinarians in animal experimentation goes back at least into the latter half of the nineteenth century when experiments on animals became a matter of public concern. Veterinarians were particularly disturbed that in France fully conscious animals were being used for physiological experiments and for surgical practice. This general concern led to the passage in 1876 of the Cruelty to Animals Act, which has dominated British thinking and practice for 100 years despite the enormous advances that have been

made in science, and particularly in biology and anesthesia, during that time.

The Cruelty to Animals Act was intended to permit experiments on vertebrate animals—that is to say, it permits the infliction of pain on animals for scientific purposes but with safeguards. The term *experiment* is not defined under the act, but it has come to mean a procedure that is calculated to cause pain when carried out on a living vertebrate animal to test a hypothesis or to provide unknown information—in other words, to answer a scientific question. Demonstrations on live animals, mostly undertaken to instruct undergraduates in physiology, also are covered by the act. Experiments on animals are usually permitted only in universities, research institutes, and on the premises of commercial firms, although provisions exist for experiments to be conducted on farms or under natural conditions where necessary. About 600 places are registered for the conduct of experiments.

LICENSING PROCEDURES

To carry out an animal experiment a scientist must have a license from the Home Office, which is the Department of State responsible for administering the act. Licenses are given only to scientists or senior technicians and are obtained by application to the Home Office. The application must be recommended by a professor of certain medical sciences and also by a president of one of several learned societies. The license permits only experiments that are carried out completely under anesthesia, in which the animal is killed before it recovers consciousness. In some experiments an anesthetic is unnecessary or would conflict with the purpose of the experiment. An exemption from the use of anesthetics is granted in these cases by obtaining a Certificate A.

There are occasions when it is necessary to anesthetize an animal and to allow it to recover. Exemption from the requirement to kill an animal before it regains consciousness is granted by obtaining a Certificate B. Authority to use animals for demonstrations is granted with a Certificate C. Cats, dogs, and Equidae have always had a special position, and experiments on these animals require separate permission, which also is granted by certificates. All of these certificates, which contain limitations on the procedures that may be done, are obtained by application to the Home Office in a similar way to the application for licenses. Holders of licenses and certificates are required to declare annually to the Home Office the number of experiments they have undertaken, and an analysis of these statistics is submitted to Parliament and published each year.

The act is administered by 15 inspectors who have medical or veterinary qualifications. Inspectors interview existing and prospective license holders; discuss new procedures with them; and check premises, animal

husbandry practices, and the animals under experiment to ensure that the welfare of the animals is safeguarded and that legal provisions are met. Although the inspectorate has legal powers, it is not a police force; inspectors are administrators and advisers to the Home Office and to the scientific community. The Home Secretary also receives advice from the Advisory Committee on Animal Experiments. This committee, which was reformed in 1979, has, among others, two members with veterinary qualifications.

Although there are about 20,000 persons licensed to perform animal experiments in Britain today, only about 12,000 are actively engaged in this work. In 1981, the last year for which figures are available, there were 4,344,843 animal experiments (Command 8657, 1982). Most of these (80 percent) were carried out with rats and mice; 6,186 monkeys, 13,459 dogs, 8,016 cats, and 434 equine animals also were used. Many animals are used in association with the pharmaceutical industry, and in 1981 more than half the experiments reported were performed by one-fifth of the license holders, working for commercial concerns.

HISTORICAL BASIS FOR BVA POLICY

General Information

A number of problems arise in applying the 1876 Cruelty to Animals Act today. For example, the system of licensing, which worked well in a small scientific community where most of the members were known to each other, is no longer appropriate. The act contains no definition or evaluation of pain—a problem referred to later in this paper. There is also no definition of what constitutes an experiment, and the definition that has evolved is not entirely satisfactory. There are a number of scientific procedures that cause pain in animals, but since they do not ask a question they are not considered experiments under the act. An example of this is the use of animals for the passage of viruses and tumors. In 1876 most animal experiments were a surgical or physiological nature. Animals were not used to test drugs and vaccines, and the LD₅₀ test, which has recently caused so much concern, had not been devised. Thus, although it was contemplated at the time that most experiments would be done under anesthesia, the vast majority are now done without it.

Control animals, which accompany the experimental animals throughout the procedure but which may themselves receive no painful treatment whatsoever, are not included under the terms of the act nor does the act apply to the breeding and supply of animals for experimental purposes. Protection of these animals is accorded under the Protection of Animals Act of 1911, which excludes anything lawfully done under the Cruelty to Animals Act. Lastly, in their concern to protect

animals from those who would want to practice surgery on them, the legislators of the nineteenth century specifically prohibited the use of animals for the acquisition of manual skill. Thus, the use of animals by surgeons to become proficient in such techniques as microsurgery, which will save human lives and restore bodily function, is prohibited.

The number of animal experiments increased from about 480 in 1878 to 46,073 in 1906, and public concern grew. A Royal Commission on animal experiments was set up in 1906 under the chairmanship of Sir John McFadyean, Principal of the Royal Veterinary College, London. The commission reported in 1912. Among its recommendations was the proposal that the Home Secretary should be advised by an advisory committee. The most important recommendation referred to pain, and as a result new wording was added to each Home Office license to the effect that if an animal on experiment is suffering severe pain that is "likely to endure" it shall be painlessly killed, even if the object of the experiment has not been attained. The wording "likely to endure" is important. Three of the eight members of the commission had reservations; they thought that animals suffering severe pain should be killed at once (Hume, 1947).

In line with the expansion of science, the usage of animals steadily increased, and in 1943 the total number of animal experiments passed the 1,000,000 mark. At this time scientists recognized that the uniformity and quality of animals available for research was not satisfactory and a Conference on the Supply of Experimental Animals was set up. The conference included representatives from several learned societies, including the Royal College of Veterinary Surgeons and the National Veterinary Medical Association, the forerunner of the BVA (Anonymous, 1947). The conference reported to the Agricultural Research Council and the Medical Research Council, and in 1947 the latter established the Laboratory Animals Bureau, later to become the Laboratory Animals Centre, with the general aim of improving the quality of laboratory animals and advising and assisting commercial animal breeders.

The rapid postwar increase in the use of animals for experiments led to greatly increased interest in their husbandry and welfare by scientists and others. A landmark was the enunciation of the 3 R's by Russell and Burch (1959): replacement of animals by nonsentient systems wherever possible, refinement of experimental procedures to obtain humanely the best possible results, and reduction of numbers of animals used to the very minimum that will serve a useful purpose.

Littlewood Committee

In the early 1960s public concern led the government to establish a departmental committee to consider animal experimentation. This, the Littlewood Committee, had

a veterinarian as a member and received evidence from the BVA. The committee pondered the question of pain in animals and proposed that within the concept of pain three states of suffering should be recognized:

1. Discomfort (as may be characterized by such negative signs as poor condition, torpor, and diminished appetite).
2. Stress (i.e., a condition of tension or anxiety predictable or readily explicable from environmental causes, whether distinct from or including physical causes).
3. Pain (recognizable by more positive signs, such as struggling, screaming or squealing, convulsions, and severe palpitation).

Although these points can be criticized, they have the considerable advantage of simplifying and clarifying what the legislation should be about. The use of a single word such as *pain* or *suffering* clearly defined in the law would greatly facilitate its interpretation and administration. Although the Littlewood Committee concluded in its report (Command 2641, 1965) that nothing was seriously amiss, it recommended improvements it wanted to achieve by new legislation.

The law remained unchanged, but many of the Littlewood recommendations were effected administratively by the Home Office. This was possible because the 1876 Cruelty to Animals Act is loosely drawn, and so the Secretary of State for Home Affairs can exercise his discretion by administrative means. This useful lesson should be remembered when new legislation on animal experimentation is drafted. The law should be sufficiently flexible to meet both present and future requirements, requirements that may change rapidly with scientific progress.

LD₅₀ Test

More recently there has been concern about the greatly increased numbers of animals used in potency, toxicity, and safety tests on drugs and other chemicals. In 1977 the Home Secretary asked the advisory committee to look into the LD₅₀ test. Carefully planned and properly executed, this test can provide useful information in numerical form. Various national and international regulatory bodies have, therefore, come to require an LD₅₀ test of substances before issuing licenses for their use. The authority of these bodies is such that their requirements, although not always legally mandatory, tend to be regarded as such. In fact a cynic has contrasted the 3 R's of Russell and Burch with the 4 R's of a regulatory authority, which recommends procedures, requests them, and then requires them; and, finally, if the requirements are not met, rejects the data submitted.

The advisory committee reported (Report, 1979) that properly conducted LD₅₀ tests should continue, but it urged closer liaison between authorities regulating the potency and safety of drugs and the Home Office so that the welfare of animals might receive more consideration. In this the committee reflected views advanced earlier by the BVA and the Laboratory Animal Science Association (Seamer, 1977). The committee also recommended that experiments on primates be subject to the same safeguards as those for dogs, cats, and Equidae, and, again, because of the flexibility of the 1876 act, the Home Office has effected this recommendation administratively.

Parliamentary Activity

During the last 10-15 years there have been a number of attempts, mostly by way of private members' bills in Parliament, to change the legal status of animal experiments. Most of these bills were very restrictive, if not completely abolitionist, and all failed to reach the statute book. The two most notable and most recent were the Halsbury Bill introduced into the Lords and the Fry Bill introduced into the House of Commons in 1979. Although both bills failed to pass, it is noteworthy that there was a shift from the extreme views of abolitionists and experimentalists, so that a redrafted version of the Halsbury Bill received support from both groups. Before the 1979 general election the three major political parties included in their manifestos proposals to revise the law on animal experiments; these were also a feature of the 1983 election manifestos. After the 1979 election the Conservative Government repeatedly affirmed its intention to introduce new legislation, and the Home Office advisory committee made proposals for changes in the law (Report, 1981). However, the government decided not to act until the Council of Europe Convention on the Protection of Animals used for Experimental and Industrial Purposes had been finalized.

Western European Activity

The legislation on animal experimentation in 21 Western European countries (all member states of the Council of Europe) has been summarized by Erichsen (1982). Lichtenstein does not permit animal experiments, while in six other member states regulatory legislation is minimal or nonexistent (Cyprus, Greece, Malta, Portugal, Spain, and Turkey). The remaining 14 states (Austria, Belgium, Denmark, Federal Republic of Germany, France, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Sweden, Switzerland, and the United Kingdom) all have regulatory controls. The law in Ireland is essentially the same as that in Britain. Apart from the Italian law, which dates from 1941, the legislation current in the remaining 11 countries was enacted or revised after 1960.

In all 14 states permission or a license is necessary to conduct animal experiments. In some countries an experiment is defined as any scientific or industrial procedure performed on a live animal, regardless of whether pain, suffering, or other harm results. In other countries only those procedures that cause pain or suffering are considered experiments. In nine countries the legislation applies only to vertebrates, while in others all animal species are included.

In France, as in Britain and Ireland, a system of individual licensing for experiments is in force. In Norway, Denmark, The Netherlands, and some other countries, licenses are granted to institutions. Institutional licenses usually require the presence of a specially competent person within the organization who may delegate authority to other persons to conduct animal experiments under his supervision and guidance. A third type of license, the project license, is issued by authorities in the Federal Republic of Germany and Switzerland for each experiment or series of experiments. In Austria and West Germany a system of authorization for certain types of experiments is contained in the law itself, and these can be conducted without further formality. In Sweden all animal experiments are appraised by ethics committees with scientific and lay members before they are sanctioned. All states that have a licensing system also operate some form of inspection.

Federation of Veterinarians of the European Economic Community

The Federation of Veterinarians of Europe (FVE) of the European Economic Community represents a wide range of professional interests of veterinarians at national and European levels from those countries that form the Community (Belgium, Denmark, Federal Republic of Germany, France, Greece, Ireland, Italy, Luxembourg, The Netherlands, and the United Kingdom). Other Western European countries send observers to FVE meetings. At its meeting in Rome in October 1982, the FVE accepted the principles set out in the BVA policy document on animal experimentation. The FVE has had observer status at meetings of the Ad Hoc Committee of Experts, which is drawing up a Council of Europe Convention on animal experiments.

Council of Europe Convention

The Council of Europe represents 21 Western European countries. It aims to safeguard the European heritage and improve economic and social progress. In 1971 its Consultative Assembly produced Recommendation 621, which proposed the formation of an Ad Hoc Committee of Experts "to study problems arising out of the use of live animals for experimental or industrial purposes." The committee has worked to produce a convention. Progress has been very slow, but it now (June 1983) ap-

pears to be almost ready for approval by the Council of Ministers. The BVA has provided evidence to the British national delegation to the Committee of Experts and was also represented at a Public Parliamentary Hearing at Strasbourg in December 1982. When the convention is accepted by the Council of Europe each member country will be obliged to adopt legislation that is no less stringent.

BVA POLICY ON ANIMAL EXPERIMENTATION

It is against the background outlined above that the BVA has in recent years given much thought to the problems arising from animal experiments and their control. Initially a brief policy statement was produced, but this was considerably expanded in 1980, and some further revisions have also been made. The full current policy, as approved in March 1983, is attached to this article as an appendix.

Need for Animal Experiments

The BVA recognizes the need for animal experiments to advance biological knowledge, to improve human and animal health, and for essential safety and potency tests. Nevertheless the BVA supports the principles of the 3 R's, refine, reduce, and replace, and would welcome the replacement of animal experiments whenever this can satisfactorily be done. In a departure from the present legal requirements the BVA would require all experimental or scientific procedures that are likely to cause pain to animals to be legally controlled, for example, the production of antisera. Clinical veterinary procedures would of course be excluded. The BVA has not expressed a view on control animals, but to this writer it would seem illogical if these animals, which are frequently in cages adjacent to those on experiment, were not protected by the same legislation that covers animals on experiment. The use of anesthetized animals, which are *not* allowed to recover, for demonstrations in higher education should continue to be permitted but should be rigidly controlled and kept to a minimum. In a departure from current practice the BVA believes that in *exceptional* circumstances it should be permissible to use animals for the acquisition of manual skill, as in the case of surgeons practicing microsurgical techniques for use in man. This would mean that the animals would be anesthetized and allowed to recover. However, the BVA does not believe that normal living animals should be used by veterinary students to acquire or practice surgical skills. Rather, these skills should continue to be acquired as at present by the use of cadavers and later by supervised instruction on sick or injured animals that require treatment.

Apart from the foregoing the BVA has not expressed views about what sorts of experiments should be allowed. Proposals to conduct experiments should be ac-

cepted or refused by the Home Office aided by advice from the advisory committee. This committee is regarded as the keeper of the public conscience and should reflect what is or is not publicly desirable or acceptable at any given time, particularly in terms of new and unusual procedures and the numbers of animals used in tests.

Experimental Animals

Although not stated, the BVA believes in the equality of all animal species and would not, therefore, offer the current special treatment for cats, dogs, horses, and monkeys. Rather, it feels that all species should be treated according to their own particular physiological needs and that the conservation of wild species must be taken into account. Recognizing the concern frequently expressed in Britain that pet dogs and cats should not be stolen for use in research (even though this is believed to be a rare occurrence), the BVA would require that dogs and cats taken from the streets never be used for experiments. As a general principle it believes that animals to be used for research should be *bred* for that purpose. Exceptions to this general rule should be made in the case of farm animals and for scientific purposes, such as the study of disease in wild animals, but financial grounds alone should not be a sufficient reason for such an exception to be made. The BVA believes that a code of practice should be drawn up to maintain satisfactory standards for the husbandry and welfare of animals bred, supplied, transported, and used for experiments. Experimenters, animal technicians, and others should be legally obliged to meet the provisions of this code.

Registration of Facilities

Premises where animals are bred, kept for supply, or experimented on should be registered. As a condition of registration it should be necessary to demonstrate that proper facilities, management, and trained staff are available as well as the services of a full- or part-time veterinary surgeon. The veterinarian's duty would be to ensure the proper care and welfare of the animals. He would thus act as the "animals' friend" and as such would be responsible to the senior manager of the laboratory, who in turn would be identified to the Home Office as the person responsible for the conduct of the registered premises. The identification of an animals' friend could, if required, replace some or all of the functions of an ethics committee.

The BVA believes that the law must safeguard the welfare of animals but that its provisions and administration must recognize the value of science and of the work that experimenters carry out. The experimenter must be accountable for his conduct, but he should not, as has recently and regrettably been the case, be subjected to harassment and molestation from extremist groups.

Pain

In practical terms the problem is to evaluate, in the living animal, pain and other unpleasant sensations, such as discomfort and distress, and to determine and regulate what is acceptable. All animals, even the most simple, are sensitive to some external stimuli. Progression up the evolutionary tree increases the range of stimuli to which animals are sensitive, and in higher animals there is consciousness rather than mere sensitivity. Intelligence and memory, in addition to consciousness, exist in the very highly developed species. Somewhere along this scale certain stimuli can be recognized, by the recipients at least, as painful. Humans recognize that some stimuli are more painful than others, and this almost certainly holds true for higher animals. Similarly, pain can be of long or short duration, and who is to say whether short but severe pain is worse than milder pain of longer standing? It is paradoxical that so little is known about the interpretation of pain and suffering in animals, although in a recent book Dawkins (1980) indicates areas in which scientific progress is being made. Perhaps our understanding of pain may increase suddenly and rapidly, as it occasionally does in other areas of science.

In these circumstances the BVA had adopted as a yardstick the Littlewood categories of discomfort, stress, and pain. The BVA believes that anesthesia, analgesia, or other measures designed to alleviate pain, consistent with the standards of contemporary veterinary practice, should be applied in experimental procedures unless they are more distressing than the procedure itself or unless they would conflict with the purpose of the procedure. If a procedure is likely to cause pain, suffering, or distress of more than momentary duration of trivial intensity, which cannot be alleviated, prior authorization from the Home Office should be required. Such authorization should be given only when the procedure is judged to be of exceptional importance in meeting essential needs of man or animals. All licenses should contain provisions to ensure that any animal that suffers *severe pain* or *severe distress* that cannot be alleviated should be killed painlessly, even if the object of the experiment has not been achieved. It should be recognized that the criteria proposed by the BVA are more restrictive than those currently in force and that certain experiments currently undertaken would no longer be permissible.

AGREEMENT WITH OTHER ANIMAL WELFARE GROUPS

As a result of public discussion on animal experimentation, the BVA held consultations with other interested organizations, notably CRAE and FRAME. The principal aim of FRAME is suggested by its name: the Fund for Replacement of Animals in Medical Experiments.

CRAE—the Committee for the Reform of Animal Experimentation—is a loosely knit group representing parliamentarians and science, medicine, and animal welfare societies. During the course of discussions it became apparent that the BVA's policies were substantially acceptable to CRAE and FRAME. (The policies contained in the appendix to this article, which were accepted by the BVA Council in March 1983, have also been approved by CRAE and FRAME.) This is a significant advance because, for the first time, a large proportion of the British animal welfare community has adopted a common policy. A joint policy statement was sent to the Secretary of State of Home Affairs and to all members of Parliament, where it has been welcomed not only by the government but also by press, radio, and television commentators.

WHITE PAPER ON ANIMAL EXPERIMENTATION

Just before the June 1983 election the Conservative Government produced a white paper on animal experimentation (Command 8883, 1981). (A white paper is the recognized means by which the British Government announces, for consultation, proposals for legislation on a given topic.) The government proposals include the establishment of a new animal procedures committee of 12 members, two-thirds of whom would be drawn from medicine, veterinary science, and the other biological sciences. The committee would perform the general functions of the present advisory committee, considering matters referred to it by the Home Secretary, including questions of policy, practice, procedure, trends in experimental and scientific work, the development of alternatives to animals in experiments, and proposals for revision in the law. It will also have an enhanced role in advising on the administration of the new controls. The Home Secretary will consult with the committee on the standard conditions to which all licenses will be subject and on specified areas of work, such as cosmetics, that the Secretary regards as giving rise to special concern.

The proposals include the extension of controls to the breeding and supply of animals for experiment. The controls will extend to all living nonhuman vertebrates in accordance with the draft European Convention and will apply to any experimental or scientific procedure that may cause pain, suffering, distress, or lasting harm. The present British pain clause, prohibiting severe pain that is likely to endure, would be maintained. However, there is a categorical statement that no exceptions to this condition would be permitted, even though these are provided for in the Council of Europe Convention. The prohibition on the use of animals for the acquisition of manual skill for microsurgery will be lifted. Work on primates, but no other species, would continue to require special authorization.

The controls would be administered and supervised

by a strengthened inspectorate with medical or veterinary qualifications. Individual scientists would continue to need a license to carry out experiments, and a system of project licenses would be introduced. Applications for a personal license would require sponsorship from a senior license holder with personal knowledge of the applicant. A project license would require sponsorship from a professor in a relevant discipline, or some similar person, who would be asked to pass an opinion on the likelihood of success of the project; the possibility of success of an alternative, nonsentient method; the type of animals to be used; and the adequacy of the proposed use of anesthesia or analgesia.

Establishments at which experiments are to be performed would continue to require registration. The Home Secretary would be empowered to attach general or particular conditions to certificates of registration. Conditions would be attached to all certificates to ensure that (1) a named person or persons would have day-to-day responsibility for seeing that the conditions of registration were being fulfilled; (2) a veterinary surgeon would be available and responsible for advice on animal health and welfare; (3) adequate staff would be available for animal care; (4) care and accommodation would be appropriate for the animals; and (5) environmental conditions would be checked daily. Fees would be payable for licenses and registration.

The government welcomed the joint submission from the BVA, CRAE, and FRAME and noted that there was a large measure of agreement between their joint proposals and those of the government itself. This is indeed so. Many of the BVA proposals have been met, although not necessarily in the way envisaged in the policy statement. However, on the all-important subject of pain the government's proposal to maintain the existing pain clause is not as restrictive as the BVA, CRAE, and FRAME would wish, and these organizations will doubtless continue to press for the achievement in full of their proposals in new legislation that the newly returned Conservative Government is expected to introduce.

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APPENDIX

BVA Policy on Animal Experimentation

INTRODUCTION

Experiments on animals to advance biological knowledge, to improve human and animal health and welfare and for essential safety and potency tests have led, and continue to lead, to significant benefits for man and animals. Such experiments should continue provided that the new legislation safeguards the welfare of animals used in experiments by incorporating the provisions detailed below.

1. PROCEDURES AND ANIMALS

A procedure, for the purposes of the legislation, should be defined as any experimental or scientific act involving interference with or departure from the normal condition of well-being of an animal, which may cause pain, suffering, distress or lasting harm. All procedures should come within the scope of the legislation and it should be an offence to carry out a procedure without authority. There must be suitable exemption for the performance of veterinary procedures carried out in accordance with the provisions of the Veterinary Surgeons' Act of 1966 and amendments.

The legislation should apply to all non-human animals in the sub-phylum *Vertebrata* including the foetuses of animals and the embryonic or larval forms of other classes that have attained a stage of development capable of discrete existence outside the egg or maternal tract.

2. ACCEPTABLE PURPOSES

Procedures should be allowed only for one or more of the following purposes:—

- (a) The avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects in man, animal or plant. This purpose includes the production and safety testing of medicinal products and other substances, the quality control of foods, and the development of surgical techniques.
- (b) The assessment or detection of physiological conditions, including the diagnosis of pregnancy.
- (c) The prolongation of life of man, animal or plant.
- (d) The protection of the natural environment.
- (e) The breeding of animals.
- (f) The advancement of biological knowledge.
- (g) Some educational and training purposes. The use of anaesthetised animals which are not allowed to recover consciousness for the acquisition of manual skill should be permissible under strictly controlled conditions. Survival surgery for the acquisition of manual skill should be permitted only in exceptional circumstances such as training in micro-surgery. The use of recorded material for demonstration in higher education should be extended.

3. LICENSING OF PREMISES AND PLACES

All procedures under the legislation must be carried out on premises or places licensed for the purpose. The licence for the premises or places should specify the types of procedures which may be carried out. The licence should identify two or more people by name:—

- (a) The person or persons ultimately responsible for the care of the animals in the premises or places; and
- (b) the veterinary surgeon, either from the staff of the establishment or employed on a part-time basis, responsible for advice on animal health and welfare.

A legally enforceable Code of Practice should lay down required standards for premises, places and facilities available for the care of the animals and for the carrying out of the licensed procedures.

The Code should specify that a sufficient number of competent staff are available at all times to care for the animals, especially those that have undergone surgical interference. The Code should also specify that an animal used or intended for use in a procedure is provided with suitable and adequate accommodation, an environment, sufficient freedom of movement, and food and water appropriate to its health and well-being. The environmental conditions should be checked at least daily and the state of health of all animals in licensed premises or places should be observed sufficiently frequently and in sufficient detail to ensure their well-being in the context of the procedure. The Code of Practice should specify conditions for the transfer of animals between licence holders, or between licensed establishments during the course of, or at the end of, a procedure.

Legislation should permit the performance of procedures in open spaces and natural environments.

4. LICENSING OF PERSONS AND PROCEDURES

Licences for individuals to carry out procedures should be issued by the Secretary of State on application by the prospective licensee. The application should be counter-signed by two sponsors. The first sponsor should be the holder of a senior appointment in the biological sciences at the establishment of the applicant, who is familiar with the applicant and the facilities available. He should certify that the applicant is a suitable person to hold a licence, and that he is competent in the handling of the animals to be used in the procedures specified in the application, and is competent to perform the specified procedure or procedures and any anaesthetic or analgesic techniques to be used. The first sponsor should also certify that the procedure or procedures conform to the provisions of the legislation, with particular reference to the acceptable purpose for which the procedures are to be performed. The applicant and first sponsor may wish to consult with a non-statutory local ethical committee before forwarding the application to the second sponsor.

The second sponsor should be an independent biological scientist from another establishment whose name is listed in a register of sponsors approved by the Secretary of State. The second sponsor should certify that, in his opinion, the procedure or procedures conform to the legislative provisions, and that they are justified in the circumstances, after having considered the possibility of using alternative techniques which do not involve the use of animals. In any application involving the use of primates, the second sponsor should certify additionally that the use of primates is essential.

Strict control should be exercised over the procedures and animal species permitted on licences. When procedures are to be carried out on unanaesthetised animals, or on anaesthetised animals which are to be allowed to recover, the licence

should specify such species as may be used and should define the permitted procedures.

The recipient of a first licence should be subject to the direction and supervision of an experienced licensee, irrespective of the qualifications and training of the recipient. This first licence should normally be valid for one year only, and a report from the Supervisor to the local Inspector should be submitted and considered before the licence is renewed without the supervision condition. There should be provision for the issue of licences with longer-term supervision conditions, provided that there is always an assessment of competence after the expiry of the first year.

Variations of any licence should be made either at the request of the holder, or of the Secretary of State.

Licences should be available for inspection at all reasonable times by an Inspector.

An undergraduate or postgraduate student of any biological science should be permitted to carry out procedures on licensed premises without being the holder of a licence, provided that it is under the direct supervision of and in the presence of a licence holder, and that the animal is anaesthetised throughout the procedure and is humanely killed at the end of the procedure without regaining consciousness.

5. CONDUCT OF PROCEDURES

A procedure starts when an animal is first prepared for use in that procedure, and ends when no further observations are to be made for the purpose of the procedure.

It is reasonable to allow the re-use of animals under certain conditions. It must be decided at the end of any procedure whether the animal shall be kept alive or humanely killed, provided that it shall not be kept alive if it is likely to remain in lasting pain or distress. At the end of a procedure animals which are to be kept alive must continue to be kept subject to the conditions of the procedure and must be placed under the supervision of the veterinary surgeon identified on the licence of the premises. An animal may be exempted from these conditions if, in the opinion of the veterinary surgeon, it would not suffer as a consequence of such exemption. It may be necessary for the purposes of the procedure to set non-domesticated animals free or return domesticated animals to their normal (i.e. non-experimental) environment. This should be permitted by the licence provided that the Secretary of State is satisfied that the maximum practicable care has been taken to safeguard the animal's well-being.

When an animal is not to be kept alive, it should be humanely killed without avoidable delay.

6. PAIN, ANAESTHESIA AND ANALGESIA

The problem of defining pain, suffering or distress has not been resolved satisfactorily. However, it is possible to recognise various states of discomfort, stress or pain, both in the intensity and the duration of the suffering. For example, a very brief painful stimulus such as the insertion of a sharp needle through the skin is probably inconsequential; on the other hand, the stress imposed in the restraint and immobilisation of the animal prior to the insertion of the needle may be severe. Thus it is the recognition of the response of the animal to a stimulus that should be the criterion of suffering, rather than the nature of the stimulus itself. It is possible also to recognise differences in the origin of the suffering, whether it be from wilful neglect or incompetence, whether it be incidental to or unexpected within the procedure, or whether it be a necessary component of the procedure.

The following provides a useful guide to the recognition of the various states of suffering, based on paragraph 181 of the Littlewood Report. *Discomfort* may be characterised by such

negative signs as poor condition, torpor and diminished appetite or by positive signs such as avoidance. *Stress* is a condition of tension or anxiety which may be predicted or readily explained by environmental causes whether distinct from or including physical causes. *Pain* is recognisable, but not necessarily quantifiable, by positive signs such as struggling, screaming or squealing, convulsions and severe palpitations or by measurement of chemical changes within the body.

During any procedure, suitable anaesthesia, analgesia or other measures compatible with the standards of contemporary veterinary practice, and designed to alleviate pain, suffering or distress of whatever origin occurring during the procedure, should be applied at any time, unless they are more distressing for the animal than the procedure itself or unless they would conflict with the purposes of the procedure. If a procedure is likely to cause pain, suffering or distress of more than momentary duration or trivial intensity, which cannot be alleviated, prior authorisation by the Secretary of State should be obtained. Such authorisation should only be given when the procedure is judged to be of exceptional importance in meeting essential needs of man or animals.

All licences should contain provisions to ensure that any animal that is suffering *severe pain* or *severe distress* which cannot be alleviated should be killed even if the object of the procedure has not been achieved.

The use of curariform drugs should be prohibited, except in conjunction with anaesthesia of sufficient depth to produce loss of consciousness.

7. ACQUISITION OF ANIMALS

Animals for use in experiments should be bred for the purpose, although exceptions should be permitted for scientific reasons and in the case of farm animals. The use for experimental purposes of cats or dogs taken from the streets should never be permitted. Exceptions to the purpose breeding rule for cats and dogs should be stringently controlled: financial grounds alone should not be a sufficient reason for an exception to be made.

Animals of the species listed below which are intended for use in procedures should be obtained only from registered breeding establishments, except:—

- (a) That exemptions from this requirement may be given for specific reasons or procedures; and
- (b) that free-living varieties of the listed species may be used in a procedure where the main object of the procedure is the study of the free-living variety.

Animals of species other than those listed below should be acquired from registered establishments wherever possible. In reaching a decision to use wild animals for experimental purposes the welfare of the animals, the survival of the species and the quality of the experimental material should be taken into account: financial grounds alone should not be a sufficient reason for an exception to be made. The general source of animals intended for use in procedures which will not be acquired from registered establishments should be stated when application is made for the licence to carry out the procedure.

Listed Species

Mouse	<i>Mus musculus</i>
Rat	<i>Rattus norvegicus</i>
Guinea Pig	<i>Cavia porcellus</i>
Rabbit	<i>Oryctolagus cuniculus</i>
Dog	<i>Canis familiaris</i>
Cat	<i>Felis catus</i>
Hamster	<i>Mesocricetus auratus</i> and <i>Cricetus griseus</i>

Other species, and particularly primates, should be added to this list as soon as there is reasonable prospect of a sufficient supply of purpose-bred animals.

8. REGISTRATION OF BREEDING AND SUPPLYING PREMISES

Control of the breeding, keeping, supply and transport of animals intended for use in procedures is essential. Establishments which breed or supply animals should be registered by the Secretary of State, and a legally enforceable Code of Practice should lay down the required standards for premises breeding and supplying animals for experimental purposes. The Code should specify the standards of premises, and the facilities required before registration is granted. The numbers and competence of staff should be specified. The certificate of registration should identify the person or persons ultimately responsible for the care of the animals in the establishment and the veterinary surgeon responsible for advice on animal health and welfare in the establishment.

9. RECORDS AND RECORDING

In order to facilitate the keeping of records of animal movement and usage, canidae, felidae, ungulates and primates intended for use in procedures, should be individually identified at the earliest practicable time after birth or after being taken into a licensed or registered establishment. The identification should be in the most permanent form available for the species and nature of the individual. Full records of the identity and origin of each member of the families listed above should be kept by all licensed or registered establishments.

Records of the movement of other species should be recorded by total number only.

The records should be in such a form as to show, as far as practicable, the origin, lifetime movement, usage in procedures and disposal of all animals, either by group or individually, as described above.

All persons licensed to carry out procedures should keep records of movements of animals intended for use in their own procedures and of the usage of animals in the procedures. Records from all licensed or registered persons should be submitted annually to the Secretary of State.

10. ANNUAL REPORT

The Secretary of State should present to Parliament, annually, a report which should include at least:

- (a) The total number of procedures carried out during the previous year.
- (b) The purposes for which the procedures were carried out.
- (c) The number and species of animals used.
- (d) The number of exemptions from the basic pain condition granted during the year.
- (e) A statement of any infringements of the legislation, and the consequences.
- (f) The subjects on which the Advisory Committee had advised during the year.

11. INSPECTORS

Inspectors should continue to be recruited from mature persons holding registered medical or veterinary qualifications.

Their statutory duties should include:

- (a) The scrutiny of applications for licences in regard to the nature and purpose of the procedures to be carried out, and the assessment of the suitability of the applicants to perform such procedures.

(b) The unannounced periodic inspection of licensed and registered establishments and the inspection of those for which application has been made. Refusal of entry to an authorised inspector at any reasonable time should be an offence.

(c) Advising the Secretary of State as to the exercise of their duties.

Inspectors should have absolute discretion to order the killing of any animals considered to be suffering unduly at a licensed or registered establishment.

12. ADVISORY COMMITTEE

An Advisory Committee should be established and should consist of a Chairman and twelve members, all appointed by the Secretary of State in a personal and not in a representative capacity.

The Committee should:

(a) Keep under continuous review (i) the extent to which animals are used in procedures which may cause pain, suffering or ill-health and (ii) other matters relating to the welfare of animals used or for use in procedures.

(b) Provide the Secretary of State with such other relevant advice and guidance as they think he requires, particularly with reference to the use of alternative techniques.

(c) Consider particular procedures which come to their notice or are referred to them by the Secretary of State and advise whether or not, and subject to what conditions, such procedures are justified.

(d) Advise the Secretary of State on any relevant matters which he may refer to the Committee for their opinion.

The Committee should be composed of persons qualified by their knowledge and experience to render competent advice to the Secretary of State on any or all aspects of the matters referred to in (a) to (d) above. The members should include veterinary surgeons, biological scientists, representatives of the medical profession and lay persons.

13. APPEALS

There should be an adequate statutory procedure for appeals against a decision made by the Secretary of State, concerning licences for procedures, licences for premises and places, or registrations for establishments.

14. PUBLIC EXHIBITION

Exhibition to the general public of visual recordings of procedures on living animals should be permitted where the recordings of procedures were originally made for an acceptable purpose as defined in Section 2.

Exhibition to the general public of procedures, or recordings of procedures, on living animals made specifically for exhibition, should not be permitted except:

(a) Where the prior approval of the Secretary of State has been obtained; or

(b) where the audience consists entirely of students or workers in the biological sciences.

15. RESTRICTION ON RIGHT TO PROSECUTION

To protect licensees or holders of certificates of registration from malicious or vexatious prosecution, a prosecution against a person licensed or registered under the legislation for an offence under the legislation should not be begun except on the instructions or with the consent of the Director of Public Prosecutions.

Proceedings should be commenced within two years of the commission of the offence or within six months of the discovery of the offence.

MARCH 1983

Mr. BROWN. Thank you very much, Dr. Seamer. That is extremely helpful testimony.

May I start with a question to you to follow up on your statement. I am not well informed about the operation of the British law. Can you tell me, in addition to what you have already mentioned about its broader scope, what the mechanism for administration of the law is, enforcement of the law? Does it provide for the kind of inspections of laboratories which we have in this country?

Mr. SEAMER. Yes, sir; there are similar inspections. They are conducted by medical or veterinary qualified inspectors who work to our home office, not to our Agricultural Department. They are made usually unannounced, and the inspector has the right at any time to order the killing of any animal which he considers is suffering.

Mr. BROWN. Do you have the provisions for animal welfare committees, by whatever name they may be called, within the laboratories?

Mr. SEAMER. No; there is no statutory provision for animal care committees. I understand that some laboratories have them. There is a move to introduce them. But there is no statutory responsibility for them.

Mr. BROWN. Just through casual reading of the European press, I have noted that there seems to be a great deal more public concern in Europe and in England with regard to the welfare of animals than there is in this country. Could you clarify a little bit on that situation, what the impact of it is on scientific experimentation and so forth?

Mr. SEAMER. I think that there has been growing concern in Britain and in Europe over the past 10 years, partly because of the deliberations which have been taking place in the Council of Europe about introducing a convention for the welfare of animals on experiment.

There has been agitation in Britain for a long time for reform of the law because it is so old and because in some respects it is outdated. The Government has published a white paper, which is our way of stating the intention of the Government, and it is anticipated that a new bill will be brought in in the lifetime of the present Parliament.

Mr. BROWN. Dr. Rosenberg, you made some reference to my home State of California and the problems we have out there. Would you like to elaborate a little bit on the possible adverse effects on scientific research of the public alarm over the way in which some of the laboratories have been operated?

Mr. ROSENBERG. I hesitate to try to educate the chairman on the political situation in California. However, it is illustrative, particularly in the San Francisco Bay area, where one of the academic institutions was seeking an appropriation from the State government to build a new animal research facility and that appropriation ran into considerable political difficulty because of past problems that institution had had with alleged abuses of animals that had been used in research there.

The institution, I suppose, counterclaimed that the more modern facility would make it easier for them to provide proper care of the animals.

But the point that we wish to make is that a large body of science in the United States depends heavily upon support from the government, be it Federal, State, or in some instances, even local, and that the public has a right to demand that research which is funded or supported in any way by the government is conducted in a way that is in keeping with the public's sensibilities.

We feel that one of the purposes of animal welfare legislation, be it the Animal Welfare Act or any other, not only is to tend to the actual animals involved but also to provide the public at large with an assurance that its money is being put to proper use and not supporting activities which individuals within the public would object to. To the extent that there is any cloud over the research community, we encourage legislation which would dispel that cloud and leave the public with the necessary assurances that their concerns are being looked after.

Mr. BROWN. Well, the public in a democracy such as the United States has not only the right but the power to do all sorts of things, including sometimes some unreasonable things. It is the purpose of good legislation to try to avoid the unreasonable things and provide for the reasonable things that the public ought to be assured of.

A couple of you in your testimony—and I have forgotten just which testified to which—made some reference to the desirability of maintaining a research data center on this area within the Library of Medicine rather than within the National Agricultural Library. There is no gain saying the importance of maintaining a close relationship between the Library of Medicine, which probably is more available to most researchers than in the Library of Agriculture.

Is this a problem which can be resolved in some reasonable way? Do any of you have comments here? I hear so much about the miracles of modern data bank networking that I can't believe this is an insuperable problem.

Mr. MELBY. Mr. Chairman, perhaps I can give or make an attempt at responding. Since I am dean of the College of Veterinary Medicine, one would think perhaps at first glance the Library of Agriculture would be the most viable suggestion. I admit in all candor I do not know the operations of either of the library systems in personal detail. But I can tell you that the library in our college, which I believe is the largest of any college of veterinary medicine in the Nation, its interfaced through the various data linkages you have mentioned is primarily to that of the Library of Medicine.

So I think your perception is quite valid that perhaps a lot of institutions would be very comfortable with the Library of Medicine. But again I underscore I don't know the inner workings and nuances of the two.

Mr. BROWN. Any other comments? Dr. Steinberg?

Mr. STEINBERG. Mr. Chairman, I think that the basic information regarding biomedical testing flows through the National Library of Medicine. The well-being and proper care of the animals is fundamental to that biomedical information, particularly for those studies, of course, that involve animals, and that to separate the two would be separating two items that are interdependent upon one another and we probably might be better served if we would

expand some of the centers that already exist at NLM and then feed, possibly feed, the information to the Agricultural Library, if necessary.

Mr. BROWN. Well, I have had the opportunity to visit both facilities, and there is no question but what the Library of Medicine is more advanced and sophisticated from almost any standpoint. On the other hand, the National Agricultural Library is making rapid strides to improve the availability of its data. I see no reason why there couldn't be an arrangement worked out where both of the facilities should have the data available and it could be readily accessible to all research institutions, which I think is the ultimate purpose of it.

Mr. ROSENBERG. Mr. Chairman, we had commented on that for two reasons. One is the fact that many researchers are hooked up to either one or the other of the library systems but not both, and a large number of animals that are used in research are used in the life science research rather than animal husbandry or whatever other areas.

The other concern that we had was that, historically, the exchange of information between the two libraries sometimes needs some facilitating from the Congress. Our recommendation in the testimony was that whatever legislation emerges, make it clear that the Congress does expect those two agencies to work together.

Mr. BROWN. Well, that is a dynamic situation. That is, there are changes taking place in both setting, and I think that some proper solution can be worked out.

In case that multitude of bells confuses anyone, this is what we call, I think, a notice quorum call or else it's a quorum call with a vote following in 5 minutes after the quorum call. We will know shortly.

Let me ask this. Each of you has heard the testimony of the others, all of which I have found to be very constructive, but do any of you have any comments that you would care to make that would be based upon statements that you have heard from the other panel members, anything that you, other than a policy point of view, that you would vitally disagree with or would feel should be amplified on or something of that sort? Dr. Orlans?

Mr. ORLANS. I would like to comment further, Mr. Chairman, about the reviewer protocol of the actual experiments in order to see whether the degree of pain that the animals are suffering is appropriate, in conformity with nationally accepted guidelines.

Dr. Melby did use the word "interfere" with respect to this type of review of the animal research committees. I would like to comment on that. I don't think that it's a matter of interference. I think that it is a matter of prime responsibility that we do improve the review system for the total system of review of animal experiments, in order to see that questionable procedures, very painful procedures, are properly reviewed for humaneness and that the amount of pain is reduced in every possible way. A key way of doing this and one that is, I think, well accepted and is becoming more and more accepted by the biomedical community is that the animal research committees shall have this role.

Of interest, I think, is a survey that was conducted by the Scientists Center for Animal Welfare at the workshop in May on how to

run an effective animal care and use committee. This was a very well attended, widely acclaimed workshop. Half of the people attending responded to a survey. That was a problem just because we didn't give the questionnaires out in enough time.

But, of the 90 respondents, 85 said that they thought that it was, "Very important that there should be review of protocols by animal research committees." Three said that it was somewhat important. None said that it was not important or that these committees shouldn't do it. Two did not answer.

So I think that although this is not a cross-section of the biomedical community, because these are people who are already keen on doing a good job with their committees, it nevertheless does indicate that there is very good support.

MR. BROWN. I am sure the question of whether that is a true cross-section of the scientific community would arise.

Dr. Melby.

MR. MELBY. Mr. Chairman, just to clarify a point, I think as a matter of communication, in my testimony when I used the term "interfere," I was referring to the nonspecificity of some of the language in the present bill as it would relate to implying the Secretary of Agriculture might have powers beyond which you might have intended.

I take no issue with Dr. Orlans. I agree completely, and I think our association does, about the internal responsibilities of the internal review committee in reviewing such protocols and accept them. So I was not concerned at all about their interfering with research. Indeed, that's an ongoing activity.

MR. BROWN. Well, I think, if I understand the situation correctly, that there is still a great deal of ambiguity in the definition and evaluation measurement of pain. As a matter of fact, the House of Representatives is right now debating the question of pain in human beings, and the steps that might be taken and the justification for using heroin to ameliorate that pain.

I was very interested in Dr. Seamer's statement about the fact that the British have considered the pain factor for a number of years. Perhaps you can tell us if you have developed objective criteria by which you can determine the degree to which animals suffer pain. But I don't think it's really so important that we know precisely as that we be concerned about it.

MR. SEAMER. Yes; thank you, sir. No; unfortunately, we don't have a scale, of course, where we can measure pain. But we do from experience have knowledge of certain procedures which are more painful or likely to cause more distress than others.

Following the discussion at the other end of the table, I can say that, for example, there are certain procedures which I think would not be permitted in Britain. I believe one is—I may get the name slightly wrong—I think it's called the Noble-Collett drum, which is used for shocking rats by putting them in a centrifuge. I do not think that that would be allowed to be used in Britain today because we believe it is too cruel, really, to be permitted.

MR. BROWN. But who makes that judgment, Dr. Seamer?

MR. SEAMER. It's a complex situation. The person wishing to do the experiment would first of all make an application. This would go to the Home Office and would be considered by one of the in-

spectors. The inspector could then discuss it with the, I will call him, the licensee; that is, the would-be experimenter. If they can't reach agreement as to what is going to happen, then it would go to our advisory committee, which is a committee sitting, a nonexecutive committee which advises on these matters.

But at the end of the day the decision rests with the Department of State, the Home Office, ultimately with the Home Secretary, who would make that ruling.

Mr. BROWN. Yes, Dr. Tegeris.

Mr. TEGERIS. Thank you, Mr. Chairman. I am Dr. Tegeris, here with Mr. Brown on behalf of the National Association of Life Science Industries.

One of the earlier speakers made a statement to the effect that many scientists perform experiments which are very painful to animals and that many scientists are not familiar with any humane treatment principles for animals.

I don't know where these figures are coming from, but we take strong exception to that. I'll tell you why. It is a basic scientific principle that for the results of an experiment to be valid, all variables must be very rigidly controlled. Any scientist who is worth the paper his diploma is written on knows that pain and stress severely compromise the results of an experiment. So it would behoove all of us, as indeed it does, to make sure that our animals are very properly cared for.

As a matter of fact, in the contract toxicology industry, we consider our laboratories to be long-term pediatric hospitals. Now, there is another reason for which we are anxious to make sure that as many animals as possible survive on an experiment. Let us make the assumption that we put on test 480 animals. There are approximately 240 million human beings in this country. What that means is that every animal is a surrogate for 50,000 people. So that animal is very meaningful to us because the information that it carries, it will affect 50,000 people, and we must have as many animals as possible getting to the end of the experiment because we must have enough numbers to make valid statistical evaluations to allow us to draw the conclusions that we're after in order to ultimately guard and protect the safety and care of human beings as well as of the environment in the country.

Thank you, Mr. Chairman.

Mr. Brown. Thank you for that statement, Dr. Tegeris.

I will have to recess the subcommittee briefly to respond to those bells. Because of time pressure, I am going to excuse the panel at this point and ask the next panel to come forward.

Let me say again I think that your testimony has been outstanding this afternoon and an excellent contribution to our discussion.

The subcommittee will be in recess for 10 minutes.

[Recess taken.]

Mr. BROWN. We are informed we have a distinguished visitor, Mr. Michael Morrison, a House of Parliament Member in Great Britain. I would like for him to stand and be acknowledged. [Applause.]

We have been known to invite Members of Parliament to come up here and join us, Mr. Morrison. [Laughter.]

We have before us our last panel, and I apologize for the schedule delay due to the votes on the floor. We do appreciate the patience of the various witnesses. I will call them in the order in which they are listed.

First of all, let me say we have Mr. Stuart Proctor, Jr., who is assistant director of national affairs for the American Farm Bureau Federation; Ms. Gretchen Wyler, vice chairman, Fund for Animals; Mr. Steve Kopperud, legislative director of the American Feed Manufacturers Association; and Mrs. Christine Stevens, secretary of the Society for Animal Protective Legislation.

I perceive that we have certain advisers along with some of the witnesses. We welcome you all here.

Mr. Proctor.

STATEMENT OF STUART E. PROCTOR, JR., ASSISTANT DIRECTOR, NATIONAL AFFAIRS DIVISION, AMERICAN FARM BUREAU FEDERATION

Mr. PROCTOR. Yes, Mr. Chairman. My name is Stuart Proctor. I am assistant director of national affairs for the American Farm Bureau Federation. I would like to submit a copy of my testimony for the record and summarize my statement.

Mr. BROWN. We will appreciate that, and the full text of your testimony will be made a part of the record.

Mr. PROCTOR. Thank you.

Farmers have the enviable reputation of being compassionate stewards of their livestock. But despite our documented concern for the treatment of animals, we are currently under attack from a number of associations and individuals who make inaccurate and misleading statements about the treatment of farm animals. We feel that the same emotional arguments and the same tactics that are being used against us in agriculture are also being used now to describe the treatment of laboratory animals. We question whether Congress has been presented with sufficient evidence to substantiate the need for corrective legislation. Without such evidence, Congress is being asked to overreact to an undocumented problem.

To provide the data necessary to make legislative decisions concerning the regulation of laboratory animals, the Farm Bureau supports the 18-month study that has been referenced several times today, specifically the bill H.R. 2350.

We feel that legislative action is premature without thoroughly assessing how animals are currently being used in research. In my statement I go on and list a number of questions and a number of issues that will be resolved by the study. But I think Congressman Volkmer hit the nail on the head this morning when he asked the question, "How do you quantify the number of violations and the abuses that are going on throughout the country today?" There was no answer to that question.

The Farm Bureau will not support H.R. 5725 or other legislation on this issue until these basic questions are addressed. Answers to these questions will help determine the need for a legislative solution to this problem.

We feel that if legislation is necessary, it should be specific, targeted at specific areas. We feel the problems associated with the

treatment of laboratory animals could be better handled with more diligent enforcement of current regulations. Current regulations should be properly implemented before additional legislation is passed.

If current regulations are ineffectively administered, we question why additional legislation and additional regulation will be any more effectively carried out.

Congress and this administration have given low priority to enforcement of the Animal Welfare Act by steadily reducing APHIS's budget. It seems inconsistent for Congress now to say this is a high-priority issue which needs additional attention, legislation, and regulation.

If there is a problem, APHIS should be given enough funds to properly enforce the act.

That completes the summary of my statement.

[The prepared statement of Mr. Proctor appears at the conclusion of the hearing.]

Mr. BROWN. Well, we thank you very much, Mr. Proctor, for that statement, and it contains a great deal that we can agree with, I am sure you know.

Ms. Wyler.

Ms. WYLER. Thank you, Congressman Brown. My name is Gretchen Wyler. I am vice chairman of the 250,000-member Fund for Animals and sharing my time today is Dr. Herbert Rackow.

STATEMENT OF HERBERT RACKOW, M.D., DIPLOMATE, AMERICAN BOARD OF ANESTHESIOLOGY; PROFESSOR EMERITUS, COLLEGE OF PHYSICIANS AND SURGEONS, COLUMBIA UNIVERSITY; REPRESENTING SCIENTISTS GROUP FOR REFORM OF ANIMAL EXPERIMENTATION

Mr. RACKOW. My name is Herbert Rackow. I am a retired physician, diplomate of the American Board of Anesthesiology, and professor emeritus of the College of Physicians and Surgeons, Columbia University.

My statement is on behalf of the Scientists Group for Reform of Animal Experimentation and is in favor of prompt enactment of H.R. 5725.

All of the members of this group are either physicians, veterinarians, or research scientists.

I would like to submit a more detailed statement for the record.

Mr. BROWN. Dr. Rackow, we welcome your more detailed statement, and it will be made a part of the record.

Mr. RACKOW. Thank you. I will discuss only the animal research committee as provided for in the bill. The need for an animal research committee is very well described in "Whistleblowing in Biomedical Research, 1981." This study concerned human experimental subjects. It was sponsored by three groups: The President's Commission for the Study of Ethical Problems in Medicine and Biological Research, by the American Association for the Advancement of Science, and by Medicine in the Public Interest.

It points out that scientists in a university setting are under pressure to produce results and justify more money for more research. Promotion, tenure, salary, laboratory space and help,

travel, and other professional requisites depend upon research productivity. There is a strong conflict of interest that may affect even the best of persons. The university system of governance grants almost complete autonomy to departments and individual scientists. This may result in inadequate protection for human research subjects.

If these considerations concerning research on human subjects are valid, then the need for protection is even greater when the subjects are animals.

The establishment of an effective animal research committee is a key provision of H.R. 5725. We know from past experience that NIH inspections and USDA inspections can be inadequate to ensure humane treatment of laboratory animals. In what way will the animal research committee inspections be different? H.R. 5725 brings to the inspection committee an independent, unpaid member who is not affiliated with the research facility, has no conflict of interest, and whose primary responsibility is to the welfare of the animal subjects—not to NIH and not to the USDA.

The effectiveness of H.R. 5725 in ensuring humane treatment of research animals will depend on the quality of this member of the animal research committee. I suggest that the qualifications of this person be expanded in report language to include that the person has demonstrated an active interest in animal welfare over a period of years and has no conflict of interest in representing community concern for the welfare of laboratory animal subjects.

I thank you for the opportunity to make this statement in support of H.R. 5725.

[The prepared statement of Mr. Rackow appears at the conclusion of the hearing.]

Mr. BROWN. Thank you, Dr. Rackow.

STATEMENT OF GRETCHEN WYLER, VICE CHAIRMAN, THE FUND FOR ANIMALS

Ms. WYLER. Yes, Congressman Brown. The Fund for Animals supports the bill also. I am very proud to submit to you today, from your State of California, signed statements by physicians and veterinarians supporting very strongly H.R. 5725 as a bill worthy of consideration.

Mr. BROWN. We will make that a part of the record.

Ms. WYLER. Also, Congressman Brown, I have submitted documentations which I would appreciate being put into the record.

But today I have just seen a film, and, to put it very mildly, I am very stunned by the film I saw this morning. I would like to make some comments on that, Congressman Brown, because it totally, totally relates to your fine bill.

The film will be shown all day until 5 p.m. at St. Mark's Episcopal Church, which is Third Avenue and A, Southeast. But I would like to say, Congressman Brown, that if your bill were the law of the land, the film would not exist. It did not come from Russia. This film that I saw this morning came from the University of Pennsylvania. It was painful to watch, but certainly not as painful as the animal cast of characters had to go through.

I believe the film I saw is not becoming to a civilized nation. Was this unusual? Was this isolated? I think we no longer know. That's why we need the Brown bill.

The Brown bill requires training sessions for scientists and technicians in methods to limit animal pain and distress. If there were a Brown bill, this film would not exist, because there was no effort in this film to even limit distress. The pain seems, on the contrary, to provide entertainment and merriment to the researchers on this film.

The Brown bill requires that pain-relieving drugs never be withheld longer than necessary. In the film I saw this morning, it was necessary to use pain-relieving drugs—and they were not used.

The Brown bill requires the institutional committee to be notified of any changes in practices adversely affecting the welfare of the animals. In the film I saw this morning, hammers and screwdrivers were unconscionably and incessantly used on the primates—and this was not even in the grant request. If we had a Brown bill, that would not have happened.

The Brown bill requires semiannual inspections by an animal research committee, including a veterinarian and an outside member responsible for representing community concerns for the welfare of animal subjects.

No committee, I tell you, Mr. Brown—no committee—could have passed this. There was no concern for animal welfare.

The Brown bill provides that a Federal agency suspend or revoke support for a project if animal care, treatment, or practices have not been in compliance with applicable standards. This was totally nonsterile, with cigarette ashes falling in wounds and instruments falling on the floor. I do not believe a veterinarian could have ever authorized or directed this film.

Your bill also permits personnel to report violations without discrimination. I would like to believe that some member of that research team would have reported that if we had a Brown bill. I would encourage this committee to consider passage of H.R. 5725. We have been given for much too long false reassurances of humane treatment historically given us by the users of animals. Your bill is not antiscience. I encourage its passage, as it would distinguish us as a more civilized nation.

Thank you.

[The prepared statement of Ms. Wyler appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Ms. Wyler.

Our next witness is Mr. Steve Kopperud, legislative director for the American Feed Manufacturers Association.

STATEMENT OF STEVEN L. KOPPERUD, LEGISLATIVE DIRECTOR, AMERICAN FEED MANUFACTURERS ASSOCIATION

Mr. KOPPERUD. Thank you very much, Chairman Brown.

I, too, would like to briefly summarize my statement and ask that the full statement be placed in the record.

Mr. BROWN. Without objection, so ordered.

Mr. KOPPERUD. As you said, I am Steve Kopperud, legislative director for the American Feed Manufacturers Association. For over

75 years AFMA has been the national trade association representing the Nation's animal feed manufacturers. Members of the association produce more than 70 percent of the primary formula livestock and poultry feed sold in the United States.

In addition, some AFMA members raise large numbers of food-producing animals.

AFMA is proud of its longstanding concern for the proper treatment of all animals. Our official policy simply states, "AFMA is committed to the humane and compassionate care of all animals." AFMA is vitally concerned that animals used in all research are treated in accordance with the highest professional standards.

AFMA has vital interests in animal nutrition research, in many cases on a cooperative basis with both public and private facilities. But AFMA is also concerned that Congress not act in a manner which might ultimately and unintentionally place barriers in the path of biomedical research through increased bureaucracy or act precipitously or unnecessarily to correct wrongs which may not exist to the extent some may contend.

Chairman Brown's public support for necessary animal research and his assurances that H.R. 5725 is in no way intended to halt the use of necessary research using animals which satisfies AFMA's concerns over the intent of this bill.

However, AFMA must question the need for this legislation. As has been said today on several occasions, there is no verifiable record of the alleged widespread abuse of lab animals. AFMA has long supported legislation to investigate current lab animal care standards as a method of discovering any actual inhumane treatment, prior to taking congressional action.

More important, however—and I stress that—if remedial action is necessary should such a study be undertaken, then it is logical that the time, the money, and the effort that is being expended on H.R. 5725 and similar legislation might be more productively focused on raising the priority of the Animal Welfare Act both within Congress and the administration in its enforcement within FDA.

AFMA undertook an independent review of the Animal Welfare Act and has concluded that the Secretary of Agriculture currently has sufficient legal authority to implement all but one of the statutory requirements on the use and treatment of lab animals, as proposed by H.R. 5725.

In writing the Animal Welfare Act, it is clear that Congress intends the Secretary to have the broad authority necessary to carry out the purpose of the act; namely, "to ensure that animals intended for use in research facilities are provided humane care and treatment."

Let me briefly look at four of the major provisions of H.R. 5725 and the status of those proposals under the current AWA. Annual compliance assurances by research facilities: H.R. 5725 would require yearly assurances by the research facility that it is in compliance with humane standards of animal care, especially in any practice involving the administration of pain to an unanesthetized animal. A proviso to section 13(a) of the Animal Welfare Act, 7 U.S.C., subsection 2143(a) provides that authority now.

Animal research committee. Chairman Brown's bill would order the establishment of internal animal research committee by each research facility. Our review shows no difference between H.R. 5725 and current authority. Indeed, current regulations allow for the Secretary of Agriculture to use animal research committees in lieu of or in addition to attending veterinarians. It is apparent the Secretary was given the implied or inherent authority to require such panels.

While it must be recognized that many research facilities currently have such committees voluntarily, the precedent has already been set by other agencies, including NIH and FDA.

Inspection provisions. H.R. 5725 calls for the inspection results of the animal research committee to be made available for review by USDA inspectors. The Secretary has the authority to conduct inspections to see if the facility has violated law, regulation, or standard under section 16(a), 7 U.S.C., subsection 2146. No new authority would be needed.

State or local standards. 5725 would not preempt the States rights to pass stricter regulations. The current AWA allows for State regulation. This section allows the Secretary to cooperate with the States in carrying out rules, regulations on animal welfare.

It appears the only administrative change which cannot be made by the Secretary is to impose the criminal penalties for release of trade secrets by any member of the animal research committee. This would also apply to the criminal penalties for laboratory raids, et cetera, as have been suggested today.

It is apparent then that the Secretary has the tools to do the job. The key then is priority, manpower, training, and money. There exists no legitimate reason for legislating another set of permissions to overlay this current authority. The need is not for further legislative authority but rather for congressional, administrative, and public support for more diligent enforcement of the act.

I would ask the question that several other groups have asked today, "Why should we expect a new law and a new set of regulations would be any better enforced than the current law?" GAO has issued a report that is critical of APHIS enforcement. Senate Appropriations, in its consideration of USDA's fiscal 1985 budget, took note of the GAO study and has admonished APHIS on the overall priority given the enforcement of the AWA.

The logical route then is to seek administrative changes in the current implementation of the AWA. The Association of Biomedical Research this morning in offering to underwrite APHIS inspector training is an example of this type of cooperation. Biomedical research interests, agriculture, and animal welfare interests, using the GAO report and other developments as guides, can cooperate with USDA to achieve reasonable, mutually acceptable goals. This is preferable to a legislative tug-of-war that may go on indefinitely and where the innocent victim may be necessary in vital biomedical research.

[The prepared statement of Mr. Kopperud appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Mr. Kopperud. We appreciate your testimony and your reference to the Senate Appropria-

tions Committee. We do intend to try and give additional weight to that recommendation ourselves and hope that it will result in some improvements.

Now, Mrs. Stevens, before we take your testimony, I think we better go vote, and this will be the last vote of the evening, and I ask your indulgence, if we may.

We will be in recess for a few moments.

[Recess taken.]

Mr. BROWN. The subcommittee will be in order.

Our last witness this afternoon is Mrs. Christine Stevens. We are very pleased to have Mrs. Stevens here.

You may proceed with your testimony.

Mrs. STEVENS. Thank you, Mr. Chairman. I would like, if I may, to ask our farm adviser, Mr. Donald McCaig, to precede me on this panel, which includes farm interests.

STATEMENT OF DONALD McCAIG, YUCATEC FARM, WILLIAMSVILLE, VA

Mr. McCAIG. I would like to thank the chairman and the subcommittee for allowing me to testify. My name is Donald McCaig. My home is in Highland County in Virginia's Sixth Congressional District. I am a sheep farmer and a writer. I belong to the Virginia Sheep Breeders Association, the Virginia Farm Bureau, and am president of the Virginia Border Collie Association.

My wife, Anne, and I raise commercial and purebred sheep, and I write, often on rural matters. My latest book is "Nop's Trials."

Livestock farming isn't the easiest way to make a living, and I don't know anyone who keeps stock who doesn't like and admire animals. It's a paradox. During lambing, we spend sleepless nights in the bitter cold, saving newborns who are destined for slaughter a few months later. We'll spend more than a ewe is worth doctoring her, but when she doesn't respond and is suffering, we're the ones who put her down.

In the Book of Genesis, God gives man dominion over animals. We are the sovereign authority. We decide if and how they live, where and when they die.

There may be a livestock farmer indifferent to animals in pain, but I have never met him. There may be livestock farmers who can look at these pictures of tormented laboratory animals and shrug. There may be such men.

The essence of livestock farming is attentiveness and care. Animals are valuable. You don't waste them. You don't terrify them. You don't cause them needless pain. If they are in pain, you deal with it now, not after an 18-month study period.

H.R. 5725 is a good bill. It promotes the most basic sort of animal husbandry. It should save tax revenues, and will certainly reduce animal pain. Most livestock farmers who knew its provisions would support it wholeheartedly.

Thank you.

Mr. BROWN. Thank you, Mr. McCaig. May I suggest you talk to your Congressman, also, and see if you can influence him a little?

Mr. McCAIG. Thank you, sir.

Mr. BROWN. He happens to be on the subcommittee.

**STATEMENT OF CHRISTINE STEVENS, SECRETARY, SOCIETY FOR
ANIMAL PROTECTIVE LEGISLATION**

Mrs. STEVENS. Mr. Chairman, I would like to confine my remarks, leaving my testimony in the record, to the problem that we have heard over and over again that people think there isn't any documentation to show widespread animal suffering in laboratories. Therefore, we have prepared charts, and this large one that you see on your left—I hope it will be visible to you—this is a study in which 186 institutions have been looked at under the Freedom of Information Act. We have taken the USDA reports, both the annual reports and the repeated reports of the inspectors.

Far from being a rarity, animal abuse is extremely common, as demonstrated in this survey. The data collected shows that major and repeated deficiencies or alleged violations of the minimum standards of the Animal Welfare Act by 23.7 percent of the sample of 186 institutions. Another 22 percent have less frequent major violations, 28.5 percent have only minor ones, and 1.6 percent are under investigation.

Thus, even using the most optimistic assumptions, only 24.2 percent of registered research facilities are regularly meeting the existing minimum standards of the Animal Welfare Act.

You will note there, if you can read the columns, that many of the institutions that are—these are category 1; these are the ones with major repeated deficiencies—many are AAALAC-accredited facilities, thus clearly demonstrating that the National Institutes of Health position that accreditation guarantees good animal care and treatment is untenable.

Further, 79 percent of the severely deficient institutions were rewarded by an increase in NIH funds in the second year noted. Twenty-five percent of the 44 used more animals and got more money from NIH, despite their bad record with USDA.

It is not true to say that animals, animal use is just decreasing by nature.

Further, the column on the far right gives the numbers of animals used in painful research where no pain relief was offered them. This is a very iffy column. It has not been properly enforced. It is very unreliable. Nevertheless, it's good to look at it. The curious fact—this is a curious fact, which is a measure of the urgent need for passage of H.R. 5725. Whether the person who fills out an institution's annual report is deliberately misstating the amount of unrelieved animal suffering or is simply blind to it matters little. The animals are needlessly suffering, and legislation is essential to prevent it.

Such legislation has been widely adopted by countries where laboratory animals are used extensively, and the only two major exceptions to this are Japan and the Soviet Union, where there is virtually no legislation to protect animals at all.

Now, the reason that you're hearing so much about we don't really know if there is any animal suffering is that a great deal of that is coming from the Association for Biomedical Research. It is a trade organization founded by Charles River Breeding Laboratories, a multinational, multimillion-dollar business which recently became a part of Bausch & Lomb, the big optical company. To give

you an idea of the size of the funds involved, I would quote the Boston Globe:

Charles River had about \$45 million in sales during the last twelve months and earnings of \$6.2 million. Bausch and Lomb, based in Rochester, New York, is nearly thirteen times the size of Charles River. Dr. Henry L. Foster, founder and president of Charles River, owns 29 percent of the company's stock, which would be worth about \$37.8 million if the deal goes through.

And it did.

How are these huge profits made? The answer is simple: by skillful and unrelenting promotion of the sale of the maximum numbers of animals to scientific institutions. Even animals as small and inexpensive as white mice can turn a fat profit if they are produced by the tens of millions and marketed with full-page ads in every issue of the right journals. Monkeys, of course, bring far higher prices, and Charles River trumpets their ready availability in ads which, since Bausch & Lomb took the company over, are not only full-page but full-color, too. "Don't put your research on hold," their scientists are advised, "link up with our primate that means quality. Our cyno. And any of our other 10 commonly used species."

Mr. Chairman, I see the red light is on, so I am going to cease.

Mr. BROWN. Mrs. Stevens, you may make a suitable conclusion. We're not being all that rigorous. So if you want to sort of summarize what your main points are, that will be fine.

Mrs. STEVENS. Fine, thank you.

Well, I would like then to turn to the recommendations at the end. Also, I certainly would be glad to answer any questions about these charts, which I think is a very key and essential matter, because the charts simply quantify what we already know from our own laboratory visits from many other sources, but the question has been so often raised that this is an unexplored area that we felt it was important to put it down in black and white.

There is a second chart right behind that one, Mr. Chairman, if somebody would like to move it so you can see the next batch. Those are the 44 institutions of the 186 that have the major repeated violations.

Now I would like to turn to the recommendations that, one, that the subcommittee should ask for regular reports on the measures taken by Veterinary Services to make the Animal Welfare Act program effective.

They should also have methods of rewarding good and discouraging poor enforcement by all personnel. That is essential. Prompt reporting of deficiencies found in all federally funded institutions to the funding bodies. The memorandum of understanding is not working as well as it should. It's an excellent idea, but there needs to be oversight.

The NIH peer review panels are unaware of the findings of the U.S. veterinary inspectors. They don't know about any of this information that is there on the charts, and certainly not about the specific reports on the laboratories.

The Office of General Counsel is not doing its job on the Animal Welfare Act. The inspectors are far, far superior to the Office of General Counsel, and they deserve a good deal of scrutiny.

Further, the subcommittee should make clear to the Secretary of Agriculture that any shifting of funds away from the Animal Welfare Act will not be tolerated in the future.

The number of animal care specialists should be at least doubled, because what happens—I would like to say that it's not quite as bad as it sounds about the fleets of cars—they took away the inspectors when they had an avian flu epidemic, and there should be a solid body of inspectors who are always there so that if a disaster of that kind occurs and some of the inspectors are taken away from that work, there should be somebody there continuing to inspect the laboratories and other places.

So, Mr. Chairman, that's the main body of what I would like to say. Thank you for the opportunity to do it.

[The prepared statement of Mrs. Stevens appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Mrs. Stevens.

Without objection, the full text of your statement will be in the record.

Now I would like to have a little better understanding of how you obtained the data that's reflected in the charts. Is that based upon an analysis of the actual inspection records?

Mrs. STEVENS. That's correct. We write to USDA requesting, under the Freedom of Information Act, their reports on different institutions. And we have been doing this for, I guess, about 8 months now, and we've gotten up to the total of 186. Obviously, we should continue to do this, but when I hear people saying, "Well, there's just a few around," we find that the majority, as I say, have deficiencies in different—that's why we made these different categories. So that there was one gentleman that said there is 3,000 laboratories and he's only heard of one or two, well, if you extrapolate from 186, you get over 2,000 that have alleged violations and deficiencies under the Animal Welfare Act.

Think how much more there would be if your bill, which is so much needed, were actually in effect.

Mr. BROWN. Mrs. Stevens, as you know, the problem before us is not to convince me that the bill is needed but to convince a number of other Congressmen to the same effect. [Laughter.]

Even beyond the 50 who are cosponsoring it.

I am going to ask if any member of the panel wishes to make a comment or to seek to clarify the testimony that they have heard. Now, we have made a sincere effort to keep the panels reasonably well balanced with regard to the different points of view here. We haven't been 100 percent successful, but that was our effort. I don't want to start any fights or anything, but I am interested in a fairly balanced record, and for that reason I am going to ask any of the panel members who wish to do so to add to their comments or to address a question based on the others.

Mr. Proctor.

Mr. PROCTOR. Mr. Chairman, I would like to make a comment. I think the statistics that Ms. Stevens has provided us with are excellent, and that's just the kind of data that we need to properly analyze how animals are being treated, lab animals are being treated.

To me, though, it seems like if only 24.2 percent are regularly meeting standards of the Animal Welfare Act, that supports our position that the act is not being properly enforced and that it's a regulatory problem and one that does not need additional legislation. That's the first point I would make.

In relating to those numbers again, when you've got 25 percent who aren't complying with current standards, what's going to happen when you impose new standards and new regulations without increasing the resources for enforcement? It only means that you're going to have a higher number of violations and you're not doing anything to really solve the problem.

We don't want to appear to be unsympathetic to the other parties concerned, but again we think it's a regulatory problem and not one that requires additional legislation.

One other quick point. There is obviously a big difference of opinion here. Some people want to go the regulatory route, another group wants to go legislation. Another difference of opinion on the number of animals used in research, Dr. Randall this morning said the number is actually decreasing, Ms. Stevens says the number is increasing. Well, that's why we think the study is important, so that we can have somebody, an independent evaluation, by the National Academy of Science or some other reputable institution to tell us exactly where we are.

Mr. BROWN. Knowing what a reasonable woman Ms. Stevens is, I think she would agree with you that it would be desirable to improve the quality of the inspection that we have at the present time.

Would you like to comment on that?

Mrs. STEVENS. I certainly would. We do want to improve the quality. I would like to say in answer to Mr. Proctor also, though, that it's not just a regulatory problem. These figures come from the regulations that exist. The reason, in my opinion, that USDA has to go back so often, why these repeated deficiencies occur, is that the laboratories have not really taken the USDA seriously.

They try, the inspectors go, they have to go back. They are wasting Government funds having to go back in 24 hours or 30 days or whatever the thing happens to be. Still, they often have to actually say, "OK, we're going to write this up as a case." Then, usually, finally the laboratory pulls itself together and does something.

We need to upgrade the whole perception of this piece of legislation, which was passed, I may say, unanimously with tremendous public supports. The public expects that this is what is happening, but unfortunately the laboratories have been able to push USDA aside and have been using really very unfair methods, I may add, to do just that.

I would like to comment, too, that NIH, on those site visits that Dr. Wyngaarden mentioned this morning, according to our statistics, three of them that he said had adequate to excellent animal care, are in category 1, major deficiencies and repeated major or minor ones.

One of them, we can't even get the inspection report. That usually means that there is a case and it's under investigation.

So here are these wonderful—so-called wonderful, according to NIH—which also believes as long as AAALAC says they have accreditation, that they're just fine.

So those are representative reasons why we have to have your bill as well as solid support for USDA's inspection.

Mr. BROWN. Ms. Wyler, I can see you want to make a brief comment. [Laughter.]

Ms. WYLER. Very brief.

No; I just would like to go into the record and say that I commend Animal Welfare Institute for this chart and how shocking that our own Government hadn't put one together instead of you having to do it.

I would also like to say that I have spoken to many exinspectors, and even some that are still there. They are intimidated by the scientific community, admittedly so. They are not properly trained to be investigators in the way of animal health and care. They are intimidated, admittedly so.

I also would like to bring to your attention something I got yesterday. I think this is rather shocking. Under the law, the Animal Welfare Act, you must sign—the veterinarian who might not even see the actual experiment must just sign—just say, "Pain relievers were withheld because it would interfere." They don't even make—as you know, until your bill, they don't even have to say why.

I have in front of me Syntex Research Corp. in California admitted in this category, Mr. Chairman, 260 dogs received pain without benefit of pain-relieving drugs and 150 primates. Strangely enough, in our Government survey of that same time period, under the State of California, it said, "Zero dogs and zero primates."

So the recordkeeping here is not the least bit reflective, I would assume, from our own Government and that saddens me greatly. When in one institution in the State of California, Syntex has 150 primates receiving real pain without benefit of pain-relieving drugs, they don't even show up on this form, the annual summary of the Government.

Mr. BROWN. Thank you for that comment.

Do any of the other members of the panel wish to offer a comment at this time?

[No response.]

I might note that even Members of Congress are sometimes intimidated by the scientific community, so it's not surprising that inspectors are sometimes intimidated.

My perception is that the inspectors are going to receive more encouragement from the Congress not to be quite so intimidated and to do a more effective job.

I am encouraged by the language of the Senate Appropriations Committee report in that regard.

Ms. Wyler, this is a very brief comment.

Ms. WYLER. This is the very last question. This is my first time testifying in Washington. May I just know, as a very proud American, why you were the only one interested in your bill today? Might I just know that? Is it because they were scheduled to do a lot of other things? I am not criticizing; I am only curious.

Mr. BROWN. Well, your criticism or curiosity—

Ms. WYLER. Just curious.

Mr. BROWN [continuing]. Is quite justified. We have tried to hold this hearing while the House is in session considering a number of other bills. As the bells indicate, we are called over to vote again, and some Members get tired of this running back and forth all the time.

We did have a full complement at the beginning, which is customary, and then they kind of fade away by the end of the day.

However, I can assure you that each of the Members gets a full briefing from their staff on the results of the hearing and they consider it very carefully in their deliberations.

Ms. WYLER. Thank you.

Mr. BROWN. At this point, we will make part of the record, statements submitted by a number of parties interested in this legislation.

I want to thank all of you very much. I really believe this has been a most constructive hearing and that we've compiled a good and effective record which will be of tremendous value to us.

Since I am now called again to the floor, I am going to adjourn the hearing at this point. The subcommittee will be adjourned.

[Whereupon, at 4:31 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

UNITED STATES DEPARTMENT OF AGRICULTURE
STATEMENT OF
BERT W. HAWKINS, ADMINISTRATOR
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE
OF THE
HOUSE COMMITTEE ON AGRICULTURE
SEPTEMBER 19, 1984

Mr. Chairman, I am pleased to appear before you today to review the Department of Agriculture's (USDA) activities in regard to treatment of animals used in research and to present the USDA's views on H.R. 5725, a bill "To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals."

Appearing with me is Dr. Richard L. Rissler, Assistant Director of Animal Health Programs. Dr. Rissler has responsibility for directing enforcement of the Animal Welfare Act.

Since passage of the Animal Welfare Act in 1966, USDA has been involved in the enforcement of humane care and treatment for certain animals used in research. Under current authorities, almost all State-owned or privately-owned facilities that use animals for research must register with the USDA's Animal and Plant Health Inspection Service (APHIS). These registered facilities must also submit annual reports on the animals they use. The report must indicate whether any painful experiments were conducted and whether pain-relieving drugs were used.

Registrants must meet our minimum standards of care in providing housing, handling, sanitation, food, water, transportation, and protection against extremes of weather and temperature. Also, each registered facility must establish a program of veterinary care which meets these standards. APHIS personnel perform periodic, unannounced inspections to see that the established program of adequate veterinary care is being followed.

Federal facilities are not required to register or be inspected by APHIS personnel. However, like State-owned or privately-owned facilities, they are required to submit annual reports on animal use and abide by the same animal care and treatment standards. Federal agencies, through internal systems, monitor compliance of their laboratories.

Mr. Chairman, the Department's commitment to accomplishing the goals of the Animal Welfare Act has never been greater. In the past 2 years, we have taken several initiatives to improve our administration of the act. These initiatives were fostered by our own internal review processes; expressions of public concern, especially by humane groups; and increased awareness by the research community, including Federal agencies involved in biomedical research, of the importance of humane care and treatment of laboratory animals.

During that time, we took a hard look at our animal welfare program and decided that improvements were needed. We made some organizational changes to make us more responsive to public complaints and deal more effectively with possible trouble spots.

A new position of Assistant Director of Animal Health programs was created to direct field enforcement of the act, and animal care coordinators were assigned to each Area Veterinarian-In-Charge. These changes permit us to make better use of information furnished to us by concerned public groups and to use our own resources more effectively. We also recognized the need for better qualified inspectors and have placed increased emphasis on training inspection personnel.

In the past year, we conducted an in-depth review of our enforcement of the act as it relates specifically to research facilities. The review was directed toward determining whether our inspections provided adequate assurance that laboratory animals are receiving appropriate care and treatment. As a result, we are revising a number of our internal policy memoranda to provide more specific and uniform instructions for the people who conduct the inspections. We have just completed the first of several special training sessions for Veterinary Medical Officers who conduct inspections; these sessions are the first devoted entirely to procedures for ensuring compliance by research facilities. Also, we have established a special task force that recently traveled throughout our Northern Region to review facilities there. Over 50 percent of the registered facilities are located in this region. The findings of this task force, which covered facilities from Minnesota through New England, will be used to further improve our inspection procedures.

In addition to our internal initiatives, we have increased our cooperation with other Federal agencies involved in research. For example, we have

implemented a memorandum of understanding with the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to enhance our sharing of information, including information about deficient conditions identified by their inspections or ours. People from these agencies have also participated in training sessions with our people, and personnel from APHIS and NIH recently conducted a joint site visit at the University of California at Berkeley.

Another positive step in ensuring humane care and treatment of animals used in Federal research has been the formation of an Interagency Research Animal Committee, composed of all Federal agencies known to use animals in biomedical research. This group, with our participation, has developed a set of principles that agencies will follow in the use of animals. In addition to the standards under the Animal Welfare Act, these principles address other areas of animal care and treatment.

The full impact of some of our initiatives is just beginning to be felt, but a climate for progress in ensuring proper treatment of laboratory animals has been established. Clearly, H.R. 5725 addresses the need for the kinds of improvements we have been implementing. We believe that we are on the road to meeting most of the bill's objectives under our current authority. The initiatives on uniform enforcement and information sharing are especially significant strides being made administratively.

Mr. Chairman, efforts by the Federal community to see that animals used in research receive proper care suggest that these agencies should be able to

continue to monitor compliance of their own laboratories. Therefore, we see no need to expand the definition of "research facility" to include Federal laboratories, to make them subject to APHIS registration and inspection.

Also, we believe the bill will increase enforcement problems. For, example, deletion of the term "minimum" as the lower limit for standards of care would require new regulations. The term "minimum" has an established meaning and has proved to be enforceable in a court of law. We recommend the term be retained. Similarly, the added requirement of exercise for dogs could cause difficulty in establishing an enforceable standard.

Mr. Chairman that concludes my remarks. We will be happy to respond to any questions you and the Subcommittee members wish to ask.

STATEMENT BY

JAMES B. WYNGAARDEN, M.D.

DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Mr. Chairman and members of the Subcommittee, I am pleased to present to you this morning the views of the National Institutes of Health (NIH) on legislation concerning the care, treatment, and use of research animals and to describe to you some of the activities we have undertaken to address this issue. I am accompanied by Dr. William E. Raub, the NIH Deputy Director for Extramural Research and Training.

Let me begin by stating our general views on H.R. 5725. I think the bill reflects a good understanding of some of the fundamental concerns and needs of the biomedical research community. It seems to have been carefully crafted after a thorough review of the issues. In particular, we agree with its goal: namely, a system that provides for effective oversight of the use of animals in research; close involvement of institutional committees with the animal care and use programs of those institutions; training of administrators, scientists, and technicians in humane animal care; availability of information about potentially useful methods and models which might reduce the number of animals needed for research; and adequate and effective communication with the public about the use of animals in research. We do not agree, however, with the premise that new legislation is needed to achieve that end. I am convinced that under existing law and administrative authority we are working effectively in pursuit of goals I know we share with you, others in the Congress, and the public.

I want to acknowledge your efforts, Mr. Chairman, and those of your staff, in recognizing and attempting to take into consideration in drafting this bill some of the concerns of the Department of Health and Human Services (HHS),

NIH, and members of the research community. We believe that when animal welfare legislation reflects a clear understanding of the needs of research it is in everyone's best interests. We remain convinced that the physical and mental health and well-being of this Nation depend on biomedical research, and that the use of live animals in such research will continue to be imperative. We cannot foresee a time when this will not be the case.

At the end of last year, HHS submitted comments to the Senate Agriculture Committee expressing concern about Senate bill 657, which is similar in many respects to H.R. 5725. Two examples of differences between S. 657 and your bill reflect your understanding of those earlier HHS comments. One concern was the use of the term "methodology," a concept we believe is easily confused with the concept of protocol. Research protocols should be established and reviewed by scientists with expertise in the particular area of research in question. Your bill takes account of this concern both by using the term "practices" and by clarifying, appropriately, that the promulgation of regulations regarding experimental design is not authorized. Another concern was the ambiguous requirement for "adequate exercise" for all research animals. This would have created a problem relative to the establishment and enforcement of standards, since exercise requirements differ among species and with environmental conditions. Your bill limits this problem by confining the exercise requirement to dogs.

Turning to comments of a more general nature, Mr. Chairman, I would like to reiterate that there is already sufficient legislative and administrative authority to assure humane care and treatment and appropriate use of research animals. There is also sufficient authority for appropriate action when Federal awardees fail to observe laws, regulations, guidelines, principles, or policies. The Animal Welfare Act, administered by the Department of Agriculture (USDA), applies to research institutions. We believe that its current authority is satisfactory and allows the USDA to change procedures and standards as necessary. In addition, the Public Health Service (PHS) has used its authority to promulgate policies and guidelines relative to animal welfare for its own awardees. There is sufficient flexibility under that authority to modify this policy as needed.

To clarify this point a bit, I would like to describe briefly our current policies and procedures relative to awardee institutions where animals are used in research. Under current PHS policy, as a condition of a PHS award for research in which vertebrate animals are used, the awardee institution must provide written assurance that it has established an animal care committee to oversee care and welfare of animals used in research. Every institution for which we provide funds for vertebrate animal research in fact has such a committee, composed of a minimum of five members, at least one of whom is a veterinarian. Institutions provide us with the names and qualifications of the committee members, and are required to keep us informed when committee membership changes. Every institution using vertebrate animals in research

must include in its written assurance, which is kept on file with the NIH Office for Protection from Research Risks, a statement that the institution is committed to following the principles and guidelines of the NIH Guide for the Care and Use of Laboratory Animals (the Guide). About one-third of these institutions have sought and received accreditation from the American Association for Accreditation of Laboratory Animal Care (AAALAC), the best evidence, we believe, of full compliance with our Guide. The remaining institutions are either in full compliance with the Guide as determined by their animal care committees or are working toward compliance.

Let me just mention that our Guide is generally acknowledged as being a standard of animal care and treatment. It is updated periodically to reflect the "state of the art" in animal care. In fact, the Guide is now being revised, under contract from NIH, by the National Academy of Sciences Institute for Laboratory Animal Resources. The revision will be published next year.

In terms of compliance with our PHS animal welfare policy and with our Guide, as in other matters, NIH has relied on an assurance system. We believe that the most effective way to ensure proper laboratory animal care is to place responsibility squarely on the shoulders of researchers and officials at institutions where animals are being used. This must be a full-time concern, and only those at the institutions are there full-time. We have not felt the need to establish a system of routine inspections--a system which would in

many ways duplicate activities of other agencies, including the USDA, and for which we do not have the necessary resources. We know that the Congress and the public have not always shared our confidence in the effectiveness of our system. We are also aware that even one report of a violation causes criticism to increase. Because of our awareness of your concern and that of the public, and because we believe the public trust is important, we have initiated and participated in a number of activities designed to evaluate our assurance system; tighten our animal welfare policy; and enhance our communications with the public, with our awardees, and with other government agencies having similar responsibilities for animal care and treatment.

I would like to spend a few moments describing some of these activities, which I think illustrate that we have adequate legislative authority and are willing to take positive action which can benefit the animal subjects of research while preserving the integrity of the scientific process.

In the NIH intramural program, we recently issued a new directive on the care and use of laboratory animals. This document stipulates that each NIH Institute must have an animal research committee to advise the Institute's Scientific Director on the care and use of laboratory animals, review research proposals, and conduct animal care and handling training programs for investigators and technicians. The committee is composed of five members, including a veterinarian who actually attends the animals in that Institute and a nonscientist from outside the Institute.

In the spring of 1983, we participated with the Food and Drug Administration (FDA) and the USDA in the development of a Memorandum of Understanding designed to increase interagency communications with respect to deficiencies related to animal care and treatment. We recognized that previous communications had been inadequate, and that these agencies, with their inspection responsibilities, could be very helpful in calling attention to problems. We expect that communication will continue to improve because we, the FDA, and the USDA have a commitment to improve it. We know we must talk to each other and I assure you, Mr. Chairman, that we will continue to do so.

Over the summer of 1983, NIH site-visited a small sample of randomly selected awardee institutions. The purpose of these visits was not to evaluate every institution's animal program comprehensively but to assess the viability of our own assurance statement system. The visits were organized by the NIH Office of Extramural Research and Training and included members of intramural and extramural staffs and outside consultants, including veterinarians. There were two significant findings of the site visits: no abuses of animals were found, and our assurance statement system and our animal welfare policy were determined to be good but not perfect. As a result, we made several decisions.

First, we decided to continue a small program of random site visits. Indeed, another series of five was completed about three weeks ago. Again, these

visits are not to duplicate or replace the unannounced inspections of the USDA Animal and Plant Health Inspection Service (APHIS). They are designed to continue to emphasize to our awardees that their assurance statements are essential and must accurately reflect the status of the institutions' animal care and treatment programs. Through such site visits we will continue to assess the effectiveness of our assurance system and identify any problems which may develop with that system.

Second, we have proposed a revision of the PHS policy on animal welfare, strengthening the policy in accordance with suggestions of site visit team members and suggestions made to us through various means by the Congress and the concerned public. We published the proposed revision in a special edition of the NIH Guide for Grants and Contracts in April 1984, and solicited public comment both in writing and at three public hearings in Kansas City, Boston, and Seattle. We received over 300 comments from researchers, institutional officials, humane organizations, and individual citizens. We are currently analyzing those comments and will publish a final version of the revised policy after taking into account the views of all who commented. We expect this process to be completed by early next year.

Let me just highlight a few aspects of the proposed revision that relate particularly to H.R. 5725. Our proposal would require that institutional animal research committees (1) include a member not affiliated with the institution, and a nonscientist; and (2) be involved to some extent in the

review of proposed research protocols, with an objective being to determine that the care and use of the animals are in compliance with the Guide and other applicable regulations. I might mention, Mr. Chairman, that we have received a great deal of comment on this latter aspect of the proposed revision. As you might imagine, it was one of the more controversial aspects. The proposed revision would also require a more frequent updating of institutional assurance statements, and a specific timeframe for complying with the NIH Guide, for those institutions that do not have AAALAC accreditation.

Next, we embarked on an education campaign which began with a two-day National Symposium in April of this year and will include a series of regional workshops dealing with the PHS animal welfare policy, directed primarily to institutional animal research committees and research administrators; development of a guidebook for animal research committees; archiving of available audiovisual material related to humane research procedures, animal care and handling, etc., and development of new ones; and preparation of printed materials to increase public understanding of animal use in research.

Concern about animal welfare frequently leads to discussion of the extent to which the use of animals can be reduced. The NIH Division of Research Resources has funded a series of workshops, sponsored by the National Academy of Sciences, on the subject of what are sometimes termed "alternative" or

"adjunct" methods of research. The workshops, which were completed in late summer, brought together scientists from many disciplines, to discuss such topics as cell culture methods, mathematical/computer modeling, and the use of lower organisms in research. These workshops served to make many more scientists aware of various research methods and models that might now or in the future be available for particular kinds of research activities. It is expected that the forthcoming report of the National Academy of Sciences will include recommendations regarding the funding of research in the development of promising models and methods. NIH is funding such research and is ready to expand its efforts into promising new areas.

In closing, Mr. Chairman, I want to say that we are convinced that researchers, with rare exception, respect animals as unique and valuable resources, use them prudently, and do not abuse them. Further, we at NIH are committed to the humane care and treatment of research animals and to their appropriate, thoughtful, and careful use. The same commitment is expected from our awardee institutions.

Thank you.

I would be pleased to answer any questions you may have.

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TESTIMONY BEFORE THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH AND FOREIGN AGRICULTURE OF THE HOUSE
AGRICULTURE COMMITTEE
ON H.R. 5725,
"IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT"

ON BEHALF OF
ASSOCIATION OF AMERICAN UNIVERSITIES
NATIONAL ASSOCIATION OF STATE UNIVERSITIES
AND LAND-GRANT COLLEGES
AMERICAN COUNCIL ON EDUCATION

DELIVERED BY DR. GERALD VAN HOOSIER, JR.
PROFESSOR AND DIRECTOR, AND ATTENDING VETERINARIAN
DIVISION OF ANIMAL MEDICINE
(PROFESSOR, DEPARTMENT OF PATHOLOGY) SCHOOL OF MEDICINE
UNIVERSITY OF WASHINGTON, SEATTLE, WASHINGTON

SEPTEMBER 19, 1984

Mr. Chairman and Members of the committee, my name is Gerald Van Hoosier. I am the attending veterinarian and Director and Professor of Animal Medicare at the University of Washington. Thank you on behalf of the Joint Committee on Health Policy of the Association of American universities, American Council on Education, and the National Association of State Universities and Land-Grant Colleges, for the opportunity of appearing before your subcommittee this morning to discuss an issue of major concern: the use of animals in research. I would be remiss, Mr. Chairman, if I did not take a few moments of my allotted time to note some reluctance on the part of our universities to raise questions about this legislation, given your extraordinary record in the Congress these past many years in behalf of science research and higher education generally. We see this bill as a thoughtful attempt to address important issues about the care and treatment of animals in research. That objective is laudable and we are prepared to try to assist in making it succeed. We take this opportunity, however, to state some basic principles.

First, Mr. Chairman, we believe, as you do that wise legislation should be based on as much information as may be gathered on the subject in question. During almost this entire Congress, both the House and Senate committees responsible for biomedical research have had pending a proposal for an eighteen month study, conducted by an organization like the National Academy of Sciences, to look into all aspects of the uses of animals in research and to make recommendations for such

legislation as may be needed to assure that high standards are maintained. Some of our colleagues in the animal welfare community have said that studies are a stall. Had we full support from all sides of this issue on that study, it could have been completed by this time. We maintain that absent such a study, any proposed legislation is subject to responding to mistaken perceptions that could require legislative amendments after avoidable problems have been generated.

Second, the National Institutes of Health is engaged in the consideration of a revised set of guidelines governing the use of animals in research. All interested parties were invited to comment on these proposed guidelines. The final product should represent a balanced approach to this complex issue. We question whether legislation at this time, until those new guidelines are finalized and tested in the field, is prudent. Differences between the guidelines and the legislation, however unintentional, could cause confusion and delay reaching precisely the objective called for by the animal welfare communities.

Third, we believe that it has been generally understood by the Congress and the general public that animals are used in research because it is necessary in order to improve the health of humans and animals. While adjunct methods have been developed in recent years and the numbers of animals used in research decreased, fundamental elements of biomedical research will always require the use of animals. We do not believe the word "alternatives" is reasonable. It is not fair nor accurate to

hold out the promise that there are-or will be-research substitutes for animals-other than other human beings. In addition, it is important to note that such adjunct methods typically are developed through the conduct of research, not through research on methods of research. Congress, representing the citizenry, wants better forms of heart surgery, wants new disease preventing vaccines, wants new cures for old diseases. It would seem appropriate when there are all sorts of attacks on the use of animals in research, that the Congress, on behalf of the Nation, state as a matter of public policy the reality that, if we are to make continuing progress in the Nation's health, the use of animals is imperative. It would help too, to have the Congress denounce recent behavior, sometimes criminal in nature, to disrupt centers of science research because animals are being used.

Mr. Chairman, I am a veterinarian and a scientist, and like my colleagues in this profession, have dedicated myself to the care and treatment of animals. I would not be associated with any enterprise in which animals were treated carelessly or indifferently, where pain was not prevented wherever possible or not treated if possible.

It should be understood that animals used in research must be healthy and cared for if the research conducted is to be reliable and useful. Allegations of general mistreatment of animals in research are devoid of factual basis. While we operate in restricted circumstances, with restricted funds, improvements not only can be made, but are being made regularly at academic

health centers where research is conducted using animals. Such improvements in facilities are necessary to the science and for the humane and proper care of animal subjects. Nevertheless, these improvements require resources that are not always available. The Committee is aware of the limits of such resources and the legitimate claim of many to them. A mandate to provide "state of the art" facilities for research animals, without funds to accomplish this, would require a shifting of resources from other-perhaps equally essential, functions.

It is not difficult to find ways to significantly improve the application of current standards. As you know, APHIS is mandated to conduct inspections of facilities using animal research. Little else would be needed to achieve the Congressional goal of better oversight than to provide APHIS with adequate funding annually. There are too few inspectors, and too few of them able to devote themselves to the area of animal welfare. It may well be that we do not need more legislation, just more support for inspection and training.

We believe the current animal welfare act along with NIH standards is adequate to meet reasonable standards of care for animals in research. New legislation may not be necessary. In addition, there is no reason to believe that the new legislation would be enforced any better than present law, absent adequate support for APHIS.

We will not undertake, in this testimony, to offer a detailed analysis of the various points in the proposed legislation that we would like to have clarified and modified. If it

would prove helpful, we will submit such an analysis for the record. There are however, a few issues that are of particular concern. First, the scientific community is zealous in protecting against federal officials intruding in the actual conduct and design of research proposals. We believe Section 4(c) of the bill would reduce current prohibitions on such interference.

Further, in 4(c)(A), there is a requirement for research scholars to show that they have considered alternative to procedures that may cause distress to animals used in research. We doubt that there is any reasonable way in which investigators could demonstrate this without extraordinary consumption of time on their behalf: it is difficult to prove a negative. Also of concern is Section 4(2) that, while written as a restriction on the federal privilege of preemption, provides an invitation to states and local governments to introduce their own regulations governing animal care. Finally, while the presence of an outside member on the animal research committee is accepted by many of the members of the associations I speak for today, we believe the definitive requiring an outside member who is "responsible for representing the concerns of the community regarding the welfare of animal subjects", will cause unnecessary confrontation between the institutions and individuals and groups in the community. Mr. Chairman, we appreciate the opportunity of presenting our views regarding your bill. I would be pleased to respond to your questions and our associations welcome the opportunity to continue further discussion on legislation in this area.

Statement of Dr. John McArdle
Director, Laboratory Animal Welfare
The Humane Society of the United States

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE I am Dr. John McArdle, Director of Laboratory Animal Welfare for The Humane Society of the United States (HSUS). In representing The HSUS, I also represent our constituency of 300,000. I was trained as a researcher and earned a Ph.D. in Anatomical Sciences at the University of Chicago. I have devoted ten years to the study of animals in research, from teaching biology and anatomy to university students, to my current position of advocate for laboratory animals. I am the author of two books and several scientific papers on primate functional anatomy.

The reduction of pain and suffering endured by animals used in research in this country is a top priority for The HSUS, as is the promotion of research into the development of techniques that would ultimately eliminate the need for laboratory animals altogether. Thus, it is in the spirit of humane science that I offer my comments.

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It is now well established that the physical and behavioral environment in which laboratory animals are bred, raised, transported and housed (before, during and after any research, testing or educational procedures) has a direct, often major, influence on the physiology, biochemistry and behavior of those animals. Essentially everything the animals experience has a real or potential impact on the validity of results from each research project. Under the present system of laws, regulations and agency "guides," researchers must assume that published data and grant proposals involve laboratory animals that received appropriate optimal care, and that the studies are not biased by poor experimental design, inadequate care and maintenance, abuse, neglect, pain or distress of the research animals. Furthermore, any attempt to compare experimental results between two or more institutions must assume equivalent, optimal care in each laboratory. The Humane Society of the United States (HSUS) believes the present system of regulations, inspections, assurances and peer review has failed in a significant number of cases to provide uniformly proper care of animals used in biomedical research (e.g. the cases of (1) Dr. Edward Taub and (2) the University of California-Berkeley). By allowing less

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than optimal care of laboratory animals, the existing system has the potential to invalidate or limit the usefulness of taxpayer-funded biomedical research. The existing system may endanger the public health with faulty tests and experiments and present an unacceptable ethical cost, resulting from potential neglect or abuse of research animals. We believe H.R. 5725 will alleviate some of these concerns and encourage appropriate use of federal tax dollars supporting appropriate biomedical research.

The existing Animal Welfare Act and National Institutes of Health (NIH) Guide both stress minimally acceptable standards of care and maintenance. This is not sufficient to establish and maintain normal physiological or behavioral parameters. We strongly request a change in emphasis from simply "requirements" to "proper" requirements. Furthermore, we vigorously urge that "proper" be interpreted to mean species-specific needs and that "behavioral needs" be added to the list of variables covered by the improved standards. There is no justification for the common practice of placing a heterogeneous population of animals species into a homogeneous laboratory environment. In their natural habitats, these animals have well-defined, species-specific characteristics. These are not lost when the species are domesticated or confined in research laboratories. Most institutions presumably already have the presently required

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minimum standards. If they do not, then the research conducted in their laboratories has questionable validity.

As is obvious from human clinical experience and modern veterinary practice, lack of exercise or activity produces a variety of physical and behavioral pathologies, and retards healing in response to accidentally or experimentally induced injuries. We strongly endorse the long-overdue recognition that research animals need physical exercise in order to maintain normal baseline physiology and behavior. This requirement should not be limited to dogs, but should apply to all species (as appropriate). One method to facilitate this new requirement is to allow research animals the opportunity to engage in their natural behavioral repertoires.

Although the value of proper post-surgical and nursing care is a basic tenet of modern veterinary practice, it is not universally characteristic of biomedical research laboratories and is often absent in testing laboratories, whose goals usually are to allow the animals to die as a consequence of the testing protocols. As a graduate student in anatomical sciences, I was routinely told that post-operative nursing care and use of analgesics for my experimental animals (which were involved in surgical procedures) was not a serious concern. Revelation of the problems in the laboratories of the University of California

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in Berkeley (see Appendix) unequivocally established that the existing laws, regulations, inspections, NIH assurances and NIH peer review procedures are unable to identify or prevent the grossly inadequate conditions and lack of proper veterinary and nursing care at that institution. H.R. 5725 requires the formal recognition of these needs and provides the means to ensure their implementation. Since such procedures will improve both the quality and reliability of taxpayer-supported biomedical research, we do not understand any rationale for opposing their implementation.

The HSUS continues to be amazed at the extent to which some representatives of the biomedical research and farming communities consistently misrepresent the content and intent of H.R. 5725. This legislation clearly differentiates between interference in the intellectual freedom of inquiry of the individual researchers (a theoretical function of the existing peer review system), and oversight and review of the treatment and care of animals used in biomedical research. Few scientists have sufficient experience or knowledge in such areas as veterinary medicine, anesthesiology, and ethology to adequately provide for and monitor the care of their laboratory animals. This is a valid area of concern for the Secretary, APHIS, and the veterinarians employed to inspect for compliance with the proper

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standards included in H.R. 5725. This proposed legislation specifically states:

Nothing in this Act shall be construed as authorizing the Secretary to promulgate rules, regulations or orders with regard to design of research, outlines, or guidelines of actual experimentation by a research facility.

Scientists are still free to propose any research protocol. H.R. 5725 will only act to ensure that proper maintenance and care of laboratory animals are included. This is a prerequisite for any valid research project and should be supported by the scientific community.

It is often stated that NIH suggestions in their "Guide for the Care and Use of Laboratory Animals," peer review, and annual reports of compliance by grantee institutions are sufficient to ensure proper care and treatment of laboratory animals. However, NIH only interacts with approximately half of the laboratories registered to perform animal experimentation. Obviously, the minimally acceptable standards of NIH are not universally applied in the United States research community. Further, a common complaint heard, even within the research community, is that NIH does not apply its own standards to its own labs. In addition,

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those labs receiving funding from NIH are not subject to routine inspections to verify their written assurances. As an initial attempt to reduce biasing factors in biomedical research, we strongly believe that the proper standards included in H.R. 5725 need to be applied to all institutions and federal agencies using laboratory animals in basic research, product testing and education.

The single, most significant portion of H.R. 5725, that which distinguishes it from the presently inadequate system and which assures compliance and uniformity of proper laboratory animal care, is the requirement for an Animal Studies Committee (ASC) and the structure of that committee. There are several key features of the proposed ASC which we very strongly endorse. These include:

1. At least one member is not affiliated with and thus not biased or obligated to the research facility. The only possible mechanism to ensure compliance with the newly required proper standards of care, and that the public's legitimate concerns about laboratory animal welfare are considered, is to have such an individual, responsible for representing the local communities' interests. Since the public pays for this research and testing with its consumer and tax dollars, and supposedly

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benefits from those uses of laboratory animals, The HSUS believes it is time to open the research establishments to the refreshing light of public accountability. We request, however, that the composition of the committee be determined by a percentage of each type of representative. Rather than at least 1 of 3 be unaffiliated, we prefer that 1/3 be so designated. This will avoid having the veterinarian and outside "conscience" representatives being overwhelmed by the larger committees (with memberships of 10 to 20 individuals). Further, membership on such committees should be opened to University students, as well as animal care technicians, who are the only individuals with detailed, daily knowledge of the animals housed in each facility.

2. The committee should meet regularly and not on a schedule dictated by a single individual (i.e. the chairperson). If a serious problem arises any member of the committee should be able to schedule a meeting.

3. At a minimum, the committee should inspect all areas of the institution involved in the use of laboratory animals semi-annually. These inspections must be unannounced and include the individual research laboratories. The former is necessary to avoid simple ritual visits of temporarily sanitized and

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cosmetically acceptable facilities. The latter would prevent the practice of individual researchers secretly maintaining animals in their laboratories in order to avoid paying per diem charges to a central animal facility or raising animals in the basements of their homes. For example, both have occurred at the University of Cincinnati. Unless identified, these animals have no protection under existing laws and regulations, regardless of the species involved. We would further urge that the Secretary authorize inspectors to examine individual research laboratories rather than myopically restricting their activities to central animal rooms and facilities.

4. As now proposed by the NIH, the committee should review research methods, protocols and practices to ascertain if investigators are properly addressing such issues as humane care, behavioral needs, veterinary practices, anesthesia and analgesia. As clearly stated in H.R. 5725, this is not done to intrude on the individual scientist's freedom of inquiry or scientific decisions, but to "ensure that animal pain and distress are minimized."

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5. The provision to allow for filing of minority opinions is important and must be maintained. This is the only mechanism to ensure that serious violations will not be covered-up by a majority vote of the committee. Further, we strongly believe that the committee reports must be available for inspection by the public, to ensure compliance and that the outside member is actually reflecting the interests of the local community.

The University of Southern California (USC) presently has a committee with a structure and role similar to that proposed in H.R. 5725 and the NIH. The existence of this committee has neither slowed nor impeded the biomedical research activities at USC, but has introduced the concept of ethical responsibilities to their biomedical research community.

On August 3, 1983 Professor K.J. Obrink from the Uppsala Biomedical Center addressed the International Council for Laboratory Animal Science on the Swedish system for compulsory ethical examination of animal experiments. His abstract notes that:

Since 1979 it is compulsory for Swedish scientists to let a local ethical committee examine animal research projects before they start. The initiative was taken by scientists in Uppsala, in 1976 with a pilot experiment that

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included Uppsala University, the Swedish University of Agricultural Sciences, several state institutions and one pharmaceutical industry.

The committee was and is composed of scientists, technicians and laymen. The idea was that the committee should advise the applicant and be his or her extended conscience. A project can be started after approval of a small group of three members of the committee. The committee itself is very large so that members should be available at all places where animal experiments are performed. It was hoped that bureaucracy in this way could be avoided.

The experience as a whole is good. It has improved the communication between laboratory and society. The scientists express a positive attitude.

We fail to understand why the United States biomedical research community so adamantly seeks to maintain the existing closed-door attitudes with regard to public knowledge and participation in local research activities. In addition, we believe the general public should have input through the vehicle of civil enforcement suits. We recommend the following additions to H.R. 5725:

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Sec. -Civil Enforcement Suits

(a) Any person may commerce a civil suit on his own behalf or on behalf of any animal protected by this chapter, to compel the secretary to apply and enforce the provisions of this chapter.

(b) The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to order the Secretary to take any action necessary to apply and enforce the provisions of this chapter.

(c) The Court, in issuing any final order in any suit brought pursuant to this section, may award costs of litigation (including reasonable attorneys fees and expenses, and expert witness fees and expenses) to any party, whenever the court determines such awards are appropriate.

(d) The relief provided by this section shall not restrict any right to other or additional relief which any person may have under any statute or common law.

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The requirement that the committee establish annual sessions for training in humane methods of animal maintenance and experimentation, concepts of alternatives to traditional methods of research, and utilization of the newly established information services at the National Agricultural Library is excellent and will counter the general level of ignorance on these subjects. We believe attendance at these sessions should be mandatory for all scientific staff and graduate students. Animal care technicians and other general staff should attend the sessions on humane care. Since research faculty often automatically resort to the traditional animal model approach to answering biomedical questions, they need exposure to currently available alternative methodologies. Efforts to minimize the numbers of animals used, the degree of pain or suffering, and to seriously assess the available alternatives, should be part of all graduate student training and research faculty attitudes. A formal, mandatory series of courses could remedy this situation. Longevity of a researcher or a research program does not automatically correlate with substantial knowledge of the proper needs of the laboratory animals or to advances in relevant alternative techniques.

There is no evidence that establishment of an ASC would entail significant new costs to research facilities or their host institutions. Membership on such ASCs can be considered part of

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a faculty member's normal committee responsibilities, which are generally done gratis. The requirement for a new series of courses could be included in the normal teaching load of the respective faculty members on the ASC.

We strongly endorse the provision protecting the employment of any individual who reports violations at their respective institutions. We routinely receive information on problems at individual research laboratories. Without exception, these individuals request anonymity because they fear losing their positions.

The establishment of an information service at the National Agricultural Library should improve the quality and reliability of biomedical research in the United States by providing information on alternatives that reduce or replace animals traditionally utilized in research, refinement of existing techniques and procedures to minimize pain and suffering and focus on the increasingly serious problem of research funds and animals wasted in "unnecessary duplication of animal experimentation." Although replication is a fundamental principle of experimental science, interminable repetition and parametric tinkering are not.

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We believe such a center would accomplish several positive goals, including:

1. Conservation of research money by careful examination of the relevant issues in the planning of research proposals. By always attempting to utilize methods that minimize the numbers of animals required, the cost of individual projects could be reduced.
2. Many of the presently available alternative techniques are more reliable and more time and cost effective than the traditional methods. Animal tests for carcinogens can take three and a half years and half a million dollars to complete. Use of comprehensive non-animal alternatives would provide identical protection and take only three months at a cost of only \$25,000. This is an example of the power of the alternative techniques. When properly developed and applied, such methods provide the needed information, while more efficiently utilizing the available research funds.
3. Provide a mechanism to avoid funding unnecessary duplication of experiments, thus freeing money for valid, new studies that may provide new information, rather than encourage further insignificant parametric tinkering in fundamentally similar projects.

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Although the biomedical research community claims that the existing peer review system addresses the issues raised in H.R. 5725, there is well-documented evidence that this is not correct. We have compiled a comprehensive "Evaluation of Awarded Grant Applications Involving Animal Experimentation", which examined funded biomedical research projects to determine if scientists receiving federal funding for their research considered humane perspectives in their applications. Using the National Institute of Mental Health as an example, we found that only 62 percent of the grantees considered the appropriateness of the animal models selected for their projects, 41 percent discussed the applicability of alternatives to vivisection, 57 percent considered the efficiency of animal use (i.e. selection of the appropriate species and methods to minimize numbers used), and less than 45 percent described the adequacy of their research facilities to maintain laboratory animals and to minimize the stress to which they were exposed. Even if grantees were honest and thorough, the information needed by the peer review panels was not generally present.

There are five distinct points at which the peer review system could significantly affect the treatment and use of laboratory animals. The process of preparing, submitting and reviewing grant proposals is the most obvious point of

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influence. Additional pressure could result from: (1) direct observations of laboratories and animal facilities by research colleagues; (2) the selection and discussion of papers presented at professional meetings; (3) evaluation of papers submitted for publication in scientific journals; and (4) consideration of promoting research faculty to tenured positions.

Despite the many opportunities for the peer review system to address the concerns discussed in H.R. 5725, it is not being done. However, the peer review process will become more effective as a result of the certification required on page 7, section (c) that the appropriate aspects of individual experiments concerning care and treatment of animals must be addressed. In particular, we strongly support the requirement that every research proposal to a federal agency contain:

1. detailed justification for "any procedure likely to produce pain or distress" and evidence that all possible alternatives to that procedure were considered. This should include a detailed explanation for the rejection of any of these alternatives. Although there may be technical disagreements on how to measure pain, its presence is easily recognized and can be scaled with respect to relative intensity.

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2. evidence that a qualified veterinarian participated in the planning of the project.
3. assurances that proper anesthetics, analgesics, tranquilizers, and post-operative medical and nursing care.
4. assurances against unnecessary survival surgery.

We strongly endorse the mandated use of analgesics and requirements for post-operative medical and nursing care. These aspects of proper laboratory animal care are routinely ignored in many research laboratories. However, we are concerned by section (B), (iv), page 5. We recommend it be reworded as follows:

"(iii) against use of paralytics without surgical levels of anesthesia confirmed by central nervous system monitoring; and"

The use of paralytics without full, surgical levels of anesthesia must be banned. Further, the Act should require that central nervous system activity be monitored throughout any procedure combining paralytics and anesthetics. This is the only acceptable method to avoid the situation where an animal regains consciousness, but is still paralyzed and thus experiencing intense pain from the surgical procedures.

In its present form, The Humane Society of the United States supports H.R. 5725. We note only one major deficiency. As with the present Animal Welfare Act regulations, the provisions of H.R. 5725 would not apply and do not require the Secretary to

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extend protection to all warm-blooded animals used in research. Currently, the Secretary chooses by regulation to specifically exclude rats, mice, and birds. At the present time 85 percent of the 70 million laboratory animals killed annually in United States research and testing facilities are excluded from any legal protection. We will accomplish little if H.R. 5725 does not include these voiceless and unprotected animals within its provisions.

(The appendix is held in the committee files.)

STATEMENT

OF THE

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

on H.R. 5725

"Improved Standards for Laboratory Animals Act"

Mr. Chairman and Members of the Subcommittee:

I am Dr. Glenn Geelhoed, Associate Professor of Surgery and Director of the Surgical Research Laboratories and Transplantation Division of the George Washington University. I am pleased to be here today to speak on behalf of the Association of American Medical Colleges (AAMC) and the National Society for Medical Research (NSMR), and I am grateful to the Subcommittee for this opportunity.

Serving as the national voice for the nation's 127 medical schools, over 400 U.S. teaching hospitals, and over 70 academic and professional societies, the AAMC represents the largest single component of the nation's biomedical and behavioral research enterprise. Because the constituencies of both the

Presented by Glenn W. Geelhoed, M.D., Associate Professor of Surgery and Director of the Surgical Research Laboratories and Transplantation Division of the George Washington University, before the Department Operations, Research, and Foreign Agriculture Subcommittee of the House Committee on Agriculture, September 19, 1984.

aamc

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AAMC and the NSMR are completely devoted to the humane care and use of laboratory animals and to the conduct of research under optimum scientific and ethical conditions, we have considerable interest in H.R. 5725, The Improved Standards for Laboratory Animals Act.

Mr. Chairman, at the outset we would like to acknowledge with appreciation your significant contributions to science during your tenure in Congress. While we recognize the considerable effort of you and your staff in improving the language contained in S. 657, the companion Senate bill introduced by Senator Dole, we regret that we cannot offer our full support for H.R. 5725 at this time.

Laboratory animals play a central and critical role in biomedical and behavioral research in that virtually no major advance in medical science could have been achieved without the basic knowledge gained through research involving animals. However, over the past several years the research enterprise in this nation, which has been spectacularly successful in determining the causes and cures of many fatal and debilitating diseases, has been under steady attack by many organizations. These groups, in their legitimate yet naive concern for the well-being of laboratory animals, have painted an extremely unfair and distorted picture of what occurs in our nation's research institutions. By citing infrequent and extreme examples, they have created an unjust image of research laboratories as torture chambers where animals are mistreated and neglected. As a result, these organizations have been able to lend credibility to efforts encouraging the adoption of governmental policies that would seriously impede the progress of one of our nation's most treasured resources -- its biomedical research enterprise.

It cannot be denied that there have been incidences in some research institutions of non-compliance with existing animal care guidelines; but these have been isolated and few and far between, while strict compliance has been the rule in a very large national research program involving hundreds upon hundreds of institutions. The scientific community, as much as the animal rights organizations, is disturbed over these instances and hopes that the problems will be eradicated through better enforcement of existing guidelines and through continued reliance on the competitive technical merit and program relevance peer review system of the NIH. Scientists, too, have a vital stake in the welfare of laboratory animals. To them, animals are a precious commodity to be treated with respect and humaneness not only for ethical and moral reasons, but also for scientific and economic ones. Only healthy, well-cared for animals provide valid data; also, laboratory animals are increasingly expensive to obtain and maintain. Thus, the consequence of failure to treat animals with the utmost care is doubly expensive, invalid experimental data.

There are three very compelling reasons why the enactment of H.R. 5725, or any other restrictive animal research legislation, would be premature at this time. These arguments require elaboration before we express specific concerns with some of the provisions of H.R. 5725.

First, because we are not aware of any grave systematic deficiencies that exist within academic medical centers and research institutions in the care and treatment of lab animals, we feel that it is extremely unfair to enact legislation that will severely restrict the conduct of research involving animals. On numerous occasions, the research community has expressed support for a comprehensive study (as proposed in S. 964) to determine definitively what problems, if any, exist in this area. A detailed study, containing valid and

quantifiable data, would provide Congress with the necessary information to determine the need and content of future legislative activities in this very complex area. Absent such data, we see no need to enact legislation which will substantially alter the conduct of research in our institutions.

Secondly, we question the wisdom of enacting H.R. 5725 until the current law governing animal welfare is better enforced. The Animal and Plant Health Inspection Service (APHIS), the government agency charged with enforcing the Animal Welfare Act, has rarely, if ever, been provided with sufficient resources to ensure adequate compliance with the law. This is a conclusion on which there is complete agreement between the animal welfare organizations and the research community. The inspection service of the animal welfare program within APHIS is critical to the enforcement of the Act and in ensuring that laboratory animals are treated humanely.

Much higher appropriations are needed for APHIS to fulfill its statutory inspection responsibilities. Currently, only 6 of the 485 animal inspectors in APHIS are full-time, and the remaining 479 inspectors, because of limited resources, are only able to devote 6% of their time to the area of animal welfare. Considering that APHIS is responsible for over 3,000 research facilities in the United States, it is clear to us that its animal welfare program is severely overburdened, underfunded and understaffed. A strong national animal inspection service, with a cadre of well-trained, well-coordinated professionals to reassure the public that animals are adequately protected, is in the national interest. We therefore strongly believe that before any new legislation increasing the responsibilities of APHIS is enacted, the agency should be significantly strengthened with more personnel and more funds. Only then can a valid determination be made as to the necessity for further restrictive animal legislation.

Thirdly, we believe that Congress should postpone the enactment of any animal welfare legislation until all efforts within other governmental agencies to develop and revise existing guidelines and principles for animal care are completed. Currently, the Public Health Service, the Interagency Research Animal Committee, and the Institute of Laboratory Animal Resources of the National Academy of Sciences/National Research Council, are in the process of revising existing animal care guidelines and principles in their areas of authority or responsibility. Since some of those "guidelines" are being implemented as mandatory, it seems to us grossly premature to legislate further animal care restrictions until the effectiveness of these revised guidelines are determined. Moreover, the promulgation of these guidelines through the regulatory process should accomplish what H.R. 5725 proposes through the legislative process.

While we hold to the foregoing general observations that caution against enacting animal welfare legislation at this time, we would like to point out our concerns with some of the specific provisions of H.R. 5725.

The statement of congressional findings in Section 2 contains no acknowledgement of the vital importance of animals to medical research. Given the fact that Congress has provided strong support for biomedical research for almost four decades, we believe that it is imperative that Section 2 contain some reference to the benefits of animal research to the promotion of health for both humans and animals.

Section 2 further states that Congress finds that some alternative methods are cheaper, faster and more accurate than animal models and will "result in more productive use of Federal funds." We are not aware of any data to confirm that alternative methods, generically, are cheaper and more accurate

than animal models and we do not support the inclusion of such language. One can also rest assured that scientists, hard pressed for funds and time, readily espouse valid alternatives to animal experiments.

The language in Section 4(c) substantially modifies and expands the authority of the Secretary, deleting the current statutory prohibitions against the Secretary interfering with research protocols. The legislative history of deleting this prohibition from interference with the "performance" of actual research tacitly implies that the Secretary would now possess such authority. We do not believe that it is proper for government officials to be in the business of monitoring or interfering with the conduct of animal research.

Section 4(c)(A) further requires principal investigators to demonstrate that they have considered "alternatives to any procedure likely to produce pain to or distress in an experimental animal and shall provide details of any procedure..." This requirement could prove to be prohibitively time-consuming and burdensome. It would be extremely difficult for investigators to demonstrate that they have considered all alternative animal models for each procedure.

Section 4(c)(B) requires that veterinarians be consulted in the planning of any procedures likely to produce pain or distress. We question whether DVM's not trained in laboratory animal medicine are qualified to participate in such research planning processes. Moreover, we fear that this language may be particularly burdensome to small institutions, since there may not be an adequate number of qualified DVM's to fulfill these requirements.

Section 4(2) adds a new provision to the law stating that H.R. 5725 should not be construed as prohibiting states or other governmental subdivisions from promulgating their own animal care standards. Because of the recent flurry of activity at the state and local levels to enact restrictive animal legislation, we are concerned that this provision may only proliferate the myriad of restrictive animal laws, regulations and guidelines already on the books across the nation.

Of particular concern to the research community is the language in Section 4(3)(A) which requires the establishment of an "Animal Research Committee" (ARC) and then sets forth the duties of that committee. First, the label "animal research committee" implies that the committee will become involved in research. We would prefer to see usage of the term "animal care committee," which implies that the committee will only be involved, as it should be, in the care and treatment of laboratory animals. The requirement that "at least one member shall have no association with the facility and shall be responsible for representing community concerns regarding the welfare of animal subjects" gratuitously implies that the "outside member" on the ARC would be the only one concerned with animal welfare. Also, this language may cause enforcement problems in that it may be difficult to define which "outsiders" represent the concerns of the community.

The requirements in this section that the ARC make semi-annual inspections of all animal facilities and submit reports thereon would be unnecessarily costly, burdensome and time-consuming. Many large institutions have hundreds of animal rooms and facilities on several campuses that would be subject to inspection. Moreover, the requirement that the ARC's review research facility practices involving pain to unanesthetized animals "to ensure compliance with standards of animal care, treatment and practices and that pain

and distress to animals is minimized," severely undermines the time-honored and proven peer review process of the research institutions. The ARC in this provision is being assigned a responsibility that inherently belongs to, and can best be fulfilled by, expert scientists in a peer review context.

Finally, Section 6 prohibits the release of confidential information and proscribes fines for such unlawful activity. This section should be expanded to authorize Federal prosecution of anyone involved in interrupting federally-funded research through breaking and entering laboratories and the destruction or theft of research data, animals or equipment. Given the increased frequency of such unlawful break-ins, we believe that the law should be strengthened to prevent this violent waste of scarce federal resources.

In conclusion, despite the few specific concerns expressed above, the AAMC and the NSMR sincerely believe that the enactment of any form of animal welfare legislation at this time is premature, unwise and unnecessary. Our recommendations to this Subcommittee are as follows:

- Congress should mandate an in-depth study to determine the nature and scope of the problems, if any, and approach any animal welfare legislation with extreme caution until the impact on biomedical research has been carefully analyzed.
- Congress should substantially increase appropriations for the animal welfare program of APHIS.
- Congress should postpone consideration of any animal welfare legislation until the animal care guidelines and principles currently under revision at three governmental agencies are implemented and their effectiveness determined.

If these recommendations are fulfilled, and this Subcommittee then feels the need to enact further animal legislation, the AAMC and the NSMR would be happy to offer any assistance in the development of appropriate, effective language. However, at this time, we are unable to support any further action on H.R. 5725.

I appreciate the opportunity to express the views of the AAMC and NSMR on this critical issue, and would be happy to answer any questions you might have.



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STATEMENT IN SUPPORT OF H.R. 5725

before the

**AGRICULTURE COMMITTEE, SUBCOMMITTEE ON DEPARTMENT
OPERATIONS, RESEARCH AND FOREIGN AGRICULTURE**

U.S. HOUSE OF REPRESENTATIVES

September 19, 1984

by F. Barbara Orlans, Ph.D.

Executive Director

Mr. Chairman, members of the subcommittee, I am Barbara Orlans, Executive Director of the Scientists Center for Animal Welfare. I speak on behalf of the organization's Board of Trustees in support of H.R. 5725.

The Scientists Center for Animal Welfare is an organization of scientists concerned about animal welfare. It is non-profit and is based in Washington, D.C. The Center acts to foster humane stewardship of animals by educating scientists and the public about animal welfare. The Center's programs have focussed particularly on the welfare of laboratory animals. We are currently conducting a series of regional workshops on how to run effective Animal Research Committees. The first of this series was held at Johns Hopkins University last May, was well attended and widely acclaimed. We are organizing similar workshops in 1984-84 in conjunction with other leading universities.

The Center has published one book on humane animal experimentation (1) and is currently preparing a major book on Animal Research Committees. Over 2000 copies of the Scientists Center's Newsletter are distributed each quarter, to members, libraries, and others.

An active Board of Trustees oversees the Center's programs. It consists of nine scientists representing a broad field of disciplines. There is approximately equal representation of Ph.Ds., D.V.Ms., and M.Ds. Dr. Jean Dodds, the Chief of Hematology at New York State Department of Health in Albany is the current president.

I am a Ph.D. physiologist, resident in the U.S. for 30 years, an investigator who has used animals in research, a member of the American Society of Pharmacology and Experimental Therapeutics, author of a book on animal care, and founding president of the Scientists Center for Animal Welfare. I recently left my position of Scientific Officer at the National Institutes of Health to assume the position of Executive Director of the Scientists Center.

HR 5725 is a good bill. It is carefully worded and represents a reasonable balance between the protection of animals and the needs of legitimate research. It will not impede responsible research, but it will strengthen the Animal Welfare Act in needed areas. This distinguished

Congressional committee has an opportunity, with passage of this legislation, to make significant improvements in the welfare of laboratory animals.

The many provisions of the bill are sound. The sections dealing with eliminating or reducing animal pain are especially welcome. In my testimony, I will concentrate on two provisions of the bill about which the Scientists Center for Animal Welfare has special knowledge; 1) those covering Animal Research Committees and 2) those dealing with training of investigators and technicians on humane practices of animal experimentation.

1) Animal Research Committees

The Scientists Center for Animal Welfare believes that effective Animal Research Committees are essential. The provisions of the HR 5725 would help ensure that these important committees function well.

Some administrative unit at each federally licensed research facility must undertake the responsibility of ensuring compliance with the Animal Welfare Act. Animal Research Committees (ARCs) are an accepted and tested mechanism for discharging these obligations. Some institutions have established highly effective ARCs, others have only given lip service to federal

requirements on these matters. Unfortunately, a number of ARCs function poorly and some are only paper committees existing in name alone. What is needed is a strong stimulus to improve the effectiveness of these important committees.

HR 5725 provides such a stimulus. This proposed legislation would mandate that ARCs undertake these following duties:

- o inspect at least semi-annually all animal study areas and facilities
- o review practices involving pain to unanesthetized animals and the condition of research animals.

It is our strong conviction that ARCs must be given mandated authority. The provisions of HR 5725 are both sound and reasonable. Research institutions should have little trouble in complying.

These committees are a key link in the review process that sets the standard for humaneness of animal experiments. An effective institutional committee can profoundly influence the welfare of animals kept for research. Conversely, an ineffective committee may mean poor compliance with nationally accepted humane standards and lack of public accountability.

In order to appreciate the importance of ARC functions, it is necessary to understand the place of ARCs in the whole framework of review for animal welfare concerns and also look at their unique features. For instance, there is the investigator's own individual conscience, then there is peer review in the laboratory by the investigator's immediate colleagues, then formal institutional review by ARCs, funding agency review, editorial review prior to publication of the results, and finally, public scrutiny after publication of the results in the scientific literature. The Scientists Center for Animal Welfare has addressed these topics in a recent book (1). All these links in the chain of review need to be in place and need to work effectively if high standards of animal welfare are to be assured.

Animal welfare review performed by ARCs has a number of unique and invaluable features not found in other levels of review. Unlike USDA inspectors and NIH review committees, ARCs are on the spot locally. If action is needed to improve the welfare of certain lab animals, then local peer pressure from an ARC is often more effective than remote oversight. Members of ARCs know the local conditions, and the strengths and weaknesses of certain animal housing facilities and laboratories; they know the investigators, technicians, and support staff, and develop a useful historical perspective that can prove valuable in assessing the level of needed surveillance of any problem area. Also, an ARC can quickly respond to any deficiency in animal care and take immediate remedial action.

Some scientists claim that ARC review functions are performed adequately by USDA inspections and funding agency review committees. A federal mandate for ARCs as in HR 5275 would, they say, add an unnecessary level of bureaucracy.

On the contrary, ARC functions cannot be adequately subsumed by other mechanisms of review. USDA inspections are infrequent and resolutions of deficiencies can take a long time. Also, the review conducted by funding agencies such as the National Institutes of Health (NIH) or the National Science Foundation is slow, typically taking 9 months to complete. It is not geared for checking an immediate problem. Experience of many research facilities has shown that these committees can function effectively with minimum delay for the investigator and do not constitute an administrative burden. Evidence of this was presented at the Scientists Center's May 1984 workshop, previously mentioned.

Membership of Animal Research Committees

HR 5725 requires that ARC members be appointed by the chief executive officer of the research facility and be composed of not fewer than three members. These members must be able to assess animal care, treatment, and practices in experimental research. At least one shall be a veterinarian, and one shall have no association with the facility.

These are prudent measures. The special expertise of veterinarians regarding animal housing, nutrition, and other husbandry needs, and of animal anesthesia, surgery, and pain relief, are essential areas that must be represented.

According to HR 5725, another ARC member would have no association with the facility and would represent community concerns regarding the welfare of animal subjects. We believe some clarification of the word "facility" is needed. It is not clear whether this means just someone in a different department (facility) but still is in the employ of the institution, or whether it means that the person must have no connections with the research institution at all. We prefer the latter definition. We, therefore, recommend that the word "facility" be changed to "institution".

Already a number of institutions have appointed community representatives as members. These include the University of California, San Francisco, the Massachusetts General Hospital, Boston, and the University of Southern California, Los Angeles, among others. Such committees tend to be among the most successful of currently operating ARCs. To our knowledge, a number of others are in the process of appointing outside community members.

It is important that community members partake in the decision-making process of determining the standards of laboratory animal use. When federal dollars are involved, then public accountability is a must. Not only the scientists themselves, but also the general public must be assured that proper humane standards are maintained. Having a community member on the ARC broadens the committee's representation, helps avoid conflict of interest. Also, it encourages dialogue between scientists and the public to understand each other's viewpoints. Scientists' reasons for and methods of conducting research need to be understood.

Training in Humane Practices

HR 5725 requires that a research facility shall provide for instruction for their personnel in the humane practice of animal experimentation. Topics to be included in this training are methods that minimize or eliminate the use of animals, and methods to limit animal pain or distress. Annual training sessions would be required for scientists, technicians, and other animal care staff.

The Board of the Scientists Center for Animal Welfare strongly supports these provisions. It stands to common sense that investigators and others involved in animal experimentation should know how to conduct

experiments humanely. It is not enough for the investigators just to know the science, they must know how to care for animals properly, and how to design and conduct an experiment humanely. Good attitudes toward animals need to be developed. Investigators should have some understanding of philosophical and ethical considerations. Investigators should be trained to carefully question and justify each and every experiment that involves pain or death to an animal for the sake of medical science.

Currently, adequate training courses do not exist. Investigators are particularly poorly served. Many investigators are conducting highly invasive, pain-inflicting experiments on animals with never having taken a course on humane techniques at any point in their education. Some investigators don't even know that the Animal Welfare Act exists or that NIH has established guidelines for humane experimentation. It is a situation that defies common sense.

Training for investigators should aim to develop understanding of the value of animal life and of sensitive attitudes to protect the welfare of laboratory animals. Topics could include, among others, provisions of the Animal Welfare Act; state laws; national policies governing the use of animals for scientific investigators; animal husbandry practices; gentle handling of animals; how to select an appropriate model (sometimes it may be better if animals are not the test object at all - non-animal models may

be appropriate); design of experiments with the least ethical cost; how to minimize animal pain; how to establish the statistically correct number of animals to be used; training in surgical techniques including administration of analgesics and anesthetics and provision of post-surgical care; selection of the earliest possible end-point for an experiment so as to avoid terminal suffering (for instance to avoid the painful terminal stages of cancer); and methods of killing an animal humanely according to its species.

Two types of courses are needed for investigators, practical courses with the nuts and bolts of humane techniques, and another type covering philosophical and ethical aspects. In a very few pioneering universities, some attempt is made to weave some practical information about animal experimentation into general biology courses. Among these pioneers are the Uniformed Services University of the Health Sciences and the Naval Research Institute, both in Bethesda, MD, and also the University of Wisconsin, Madison, WI. In hardly any instances, however, do humane methods courses merit a separate identity. The Scientists Center for Animal Welfare believes that humane methods courses should be required for all persons who intend to conduct experiments on animals.

Courses covering philosophical aspects of animal issues are more prevalent than practical methods courses. According to recent estimates, some 21

U.S. colleges offer such courses. The Scientists Center for Animal Welfare compiled a listing of these in 1983, (2). Not very many biology students attend such classes, however. They are mainly available for philosophy students. According to the Scientists Center's listing, two biology departments offer such a course as against 12 in philosophy departments. In addition, there are 5 courses in veterinary schools, and one each in a psychology department and a law school. When it is considered that there are many hundreds of colleges in the U.S., and only 21 offer any instruction on animals and ethics, it can be seen there is much room for improvement.

Some courses for technicians do already exist, ably run by the American Association Laboratory of Animal Science. A 1978 listing (3) shows some 20 locations nationally where their courses are regularly given. Although more could be done in this area, by far the greatest need is for investigator training.

We believe that strong support can be found within the biomedical community for training courses on humane experimentation. Of interest is a 1984 survey conducted by the Scientists Center for Animal Welfare on the responsibilities of Animal Research Committees to conduct or advise personnel on these matters. Currently, very few ARCs assume this responsibility

perhaps because so few suitable courses are available. Anyhow, of 90 respondents in this survey, 42 (47%) said that it was very important, and 37 (41%) said that it was somewhat important for ARCs to advise personnel on training for animal welfare issues (4). Only 6 (7%) thought it was not an important function of ARCs, and 2% thought that ARCs should not assume these tasks. Three persons (3%) did not answer. Respondents were mainly veterinarians, Ph.D. and M.D. investigators, some lab animal personnel, and a few others. They were participants at a May 1984 workshop organized by the Scientists Center for Animal Welfare on ARCs and held at Johns Hopkins University.

Federal Responsibility for Training

A legislative mandate on education in humane techniques is timely, and we believe would be well accepted by both scientists and the public. It is of interest that the House and Senate have recently voted favorably on legislation to make grants for schools of veterinary medicine for the development of curricula and the provision of training in the care of animals used in research and in the development of alternatives to such use; (S. 2574). Additional legislation as proposed in HR 5725 would mean that this type of education is available not only to veterinarians, but also to investigators and animal care personnel.

Some federal initiative, backed up by federal dollars, needs to be given to help provide courses for investigators and other laboratory personnel on humane animal techniques. 5725 provides a needed start in this important matter.

Conclusion

In summary, the Board of Trustees of the Scientists Center for Animal Welfare believes that HR 5725 is a necessary piece of legislation, worthy of support. Its passage would provide the needed force to ensure that research institutions fulfill their responsibilities for animal welfare. It is of prime importance that federally-funded animal experiments are conducted with utmost care and regard for the animals.

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Prepared Statement on H.R. 5725

Before the Subcommittee on Department of
Operations, Research and Foreign Agriculture
Committee on Agriculture
House of Representatives

September 19, 1984

Mr. Chairman:

My name is Dr. Marshall Steinberg, I am the secretary of the Society of Toxicology.

The Society of Toxicology (SOT) is a nonprofit scientific organization dedicated to the furtherance of the science of toxicology. Our members are actively engaged in determining the conditions of safe use of chemicals in our environment. We are not affiliated with any trade organization, and our membership is drawn internationally from academia, government, and industry, with the largest single block of membership being from academia.

Owing to the shortness of time, there was not the opportunity to circulate this statement to the membership for approval. It, therefore, represents the opinions of officers of the Society.

The Society of Toxicology supports the principles of H.R. 5725 in ensuring the health and well-being of laboratory animals. We are pleased to note that H.R. 5725 is an amendment to the existing animal welfare act rather than a new act. This is a reflection of the existing act as a viable and important entity. But, to remain viable, the act must be upgraded to keep current with changes within laboratory animal science. It is important for changes to occur within current and established regulations rather than to start over with a new act.

By amending the animal welfare act, the Animal and Plant Health Inspection Service of the United States Department of Agriculture (APHIS-USDA) continues as the enforcement agency. Maintaining this program with APHIS-USDA will ease implementation of improved standards of animal care as APHIS-USDA potentially has the necessary experience and capabilities to oversee regulation changes.

Annual training sessions for all personnel involved with animal care and use in a research facility are also supported. This is an appropriate means to disseminate information and techniques to all individuals as well as to sensitize them to animal welfare issues. A program of this nature could also function as an effective orientation for new employees.

There are issues that we would invite your attention to and suggest modifications

The world of toxicology is complex and multifaceted. The scientific investigators range from scientists using whole animal models to those using in vitro subcellular techniques. Most often, investigators use a mixture of techniques depending upon the course of their research. Fundamentally, there are many different types of activities which conduct

biomedical/toxicological research. The research conducted includes work done at educational institutions under grant or contract, studies performed either by or for the government, the work performed in commercial organizations in support of the development of new commercial compounds, and work performed by contract laboratories for either these commercial organizations or government agencies.

The gamut of toxicological research ranges from studies of basic mechanisms of action to testing of compounds to meet regulatory requirements. While in vitro techniques have proven to be invaluable tools in basic research, they have not been the replacement that people thought they would be for safety evaluation studies using whole animals. They have proven to be an extremely valuable addition to the armamentarium of tests that are conducted for safety evaluation of agrochemicals or drugs. Therefore, it is suggested that Section 2 be amended to show that these tests may show promise of being replacements for traditional animal experiments.

There is a need for clarity of definition with respect to distress in an experimental animal, as used in the proposed legislation. Safety studies are designed to produce a toxic effect at a high dose. It is only the improperly designed study that does not produce an effect. Technically, a well-designed study would be in violation of the law and/or would require extreme documentation to accomplish that which is scientifically valid. High-dose animals do not ordinarily experience pain but do experience extreme weight loss, increased incidence of tumors, effects on organ function, and sometimes behavioral changes.

There is some question regarding the establishment of a new information service at the National Agricultural Library in cooperation with the National Library of Medicine (NLM). Biomedical information flows through NLM, and it may be a mistake to separate research animal care from the biomedical research. It would be more expedient to expand information centers already in existence at the National Library of Medicine. The facilities and expertise at NLM are available and should be utilized.

The implementation of the Good Laboratory Practices (GLPs) by a majority of the developed countries of the world has resulted in an upgrading of the practice of toxicology and the facilities used to conduct research. Fundamental to the GLPs has been the development of standard operating procedures (SOPs) following guidelines provided by the various national agencies. These SOPs provide directions that are consistent with the experience, facilities, cultural practices, and capabilities found in each institution. Even within the United States, activities meeting Good Laboratory Practice standards vary in how they implement these standards.

It is suggested that rather than the Secretary developing standards, there be provision for guidelines and each facility be required to develop standard operating procedures to implement the guidelines. These standards should ensure that animal pain and distress are minimized consistent with the relevant scientific needs of the experimental procedures. It is not reasonable to assume that the Department of Agriculture has the information or the technical expertise to develop explicit standards for the operation of the myriad facilities in this country.

Additionally, the quality assurance unit in each laboratory functions as an extension of the laboratory. The unit provides timely information to the management of the laboratory regarding the quality of the work being performed by the investigators. Prudence as well as common sense have dictated that those in a position of responsibility pay heed to the findings of the unit and even capitalize on the ability of the quality assurance process to find deficiencies. This has resulted in a healthy marriage between science and management that in turn has produced more reliable, auditable data. H.R. 5725 would benefit from the same approach.

The amendment details too many functions for the committee and makes it, in effect, an extension of government instead of an integral oversight group of the institution. The committee, as the quality assurance unit, should work as part of a team to succeed in its mission. People providing input to the committee should see their role as one of bettering the handling and treatment of animals rather than reporting on the activities of the institution. We also have some concern about the committee relating to community attitudes regarding animals rather than good veterinary practice standards. Community attitudes vary and may be a function of the more strident voices rather than being based on knowledge. The regulation should not be an impediment to considered, caring research and should not detract from the primary responsibilities of the facility veterinarian for compliance with the animal welfare act.

The requirement for separation of species needs a provision for exemption and the requirement for exercise is an issue requiring the professional judgment of the attending veterinarian. The National Cancer Institute conducted numerous bioassays with rats and mice in the same room, with no demonstrable ill-effects owing to this practice. Some research, such as inhalation studies, must by necessity house several species in separate cages, but in the same chambers.

The need to exercise dogs may be incontrovertible on an emotional basis but a review of the literature would indicate that there is no difference in the physical parameters for a dog that is penned under the provisions

of the National Research Council guidelines and a dog that is exercised according to a predetermined schedule. Attachment A contains reprints from the scientific literature supporting this statement.

The decision to provide exercise should involve professional judgment. Captive primates and pound-source dogs, for example, may have more psychological needs for exercise than their laboratory-bred counterparts. It is suggested that in the interests of good science and better understanding of the needs of the animals, there be a distinction and that the appropriate agency initiate activity to determine what differences may exist.

As indicated in the amendment, the members of the committee are required to possess sufficient ability to assess the various aspects of animal care. It is suggested that the committee possess sufficient ability for it to carry out its mandate. This would permit the assignment of various specialists to the committee and allow greater flexibility, particularly with respect to the outside member. It is conceivable that the surrounding community may not be able to provide an individual with a knowledge of animal care, treatment, and practices in experimental research.

Finally, while the citizenry rightfully desires that undue pain and distress to laboratory animals be avoided, it is understood that the same citizens desire to be protected from the potentially noxious effects of chemicals used by our society. Tremendous strides have been made in recent years in understanding the mechanisms whereby environmental agents produce their toxicity. There is no dichotomy between animal welfare and the development of the science of toxicology, and it is noted that H.R. 5725 does recognize the need to conduct research and that the use of animals may be central to that research.

The Society of Toxicology has animal welfare and legislative liaison and assistance committees that would be pleased to work with the committee members and the staff in providing scientific input and performing whatever research may be indicated.

Thank you for the opportunity to present these viewpoints.

Marshall Steinberg, Ph.D., D.A.T.S.
Secretary

(The attachments are held in the committee files.)

THE NATIONAL ASSOCIATION OF LIFE SCIENCE INDUSTRIES, Inc.

11130 Rockville Pike, Sixth Floor,
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Prepared Statement on H.R. 5725

Before the Subcommittee on Department Operations, Research and
Foreign Agriculture,
Committee on Agriculture,
House of Representatives

September 19, 1984

Mr. Chairman:

My name is Howard C. Brown, Jr. I am the Vice-President, Executive Director of the National Association of Life Science Industries, Inc. (NALSI).

I am privileged to be accompanied by Andrew S. Tegeris, M.D., F.A.C.P., D.A.B.T. Dr. Tegeris is the Vice-President of Scientific Affairs of NALSI. He also is the President of Pharmacopathics Research Laboratories, Laurel, Maryland.

NALSI is a non-profit trade association comprised on independent toxicology testing laboratories.

We very much appreciate this opportunity to present our comments on H.R. 5725.

The policy of H.R. 5725 was succinctly stated by the distinguished Chairman of the Subcommittee before the House of Representatives on May 24, 1984. Congressman Brown said, in part: "Poor animal care works contrary to the success of the research...Proper care of laboratory animals increases research integrity and accuracy, and thus benefits society." NALSI subscribes to that statement of policy.

Indeed, in the strict Code of Ethics which NALSI created and adopted earlier in the year, each member Laboratory shall "...in every respect observe the Good Laboratory Practice Regulations and the established animal-care regulations of the federal, state and local governments."

H.R. 5725 would supplement existing federal legislation and policy guidance in a unique way by authorizing the Secretary of the Department of Agriculture to promulgate professionally acceptable standards to ensure that animal pain and distress are minimized and it provides the Secretary with specific guidance.

In our comments we should like to address what appear to us to be unnecessary redundancies in the government's regulatory and inspection

programs and to explore with the subcommittee some of the practical problems that may plague the proposed Animal Research Committee.

Existing Government Animal Care Monitoring Programs

At the present time there are at least five Departments, agencies or entities of the federal government which perform or have the authority to perform, inspections of the care and treatment of laboratory animals in both federal and private commercial laboratories.

These entities include:

The Department of Agriculture. Animal and Plant Health Inspection Service/Veterinary Services;

Department of Health and Human Services, National Institutes of Health;

and the Public Health Service, and Centers for Disease Control, Center for Prevention Services, Division of Quarantine;

The Food and Drug Administration;

The Environmental Protection Agency.

In Attachment "A" hereto we summarize the responsibilities of each of the above entities.

The additional authority which H.R. 5725 would confer upon the Secretary of Agriculture makes it even more important that overlapping authority and jurisdiction be sorted out, especially in the inspection functions and reporting requirements.

It should also be noted that the governmental regulations and inspection functions are in addition to the private, professional monitoring activities to which private laboratories voluntarily submit and subscribe.

The role of the American Association for Accreditation of Laboratory Animal Care (AAALAC) and the Toxicology Laboratory Accreditation Board (TLABS) also are delineated in Attachment "A".

Protection of Confidential Data - Effect of the Animal Research Committee

We appreciate that the Bill endeavors to address the need to protect private commercial data but we believe that the protection afforded - mainly by sanctions - is inadequate. The reason for the inadequacy may stem from a lack of understanding of the ownership, or admixture of ownership, or proprietary data in a contract testing laboratory.

Although each NALSI laboratory contracts with the federal government from time to time for research or testing, the primary business for most NALSI laboratories consists of contracts with developers or manufacturers of products, such as, medical devices, prescription drugs, or chemicals used in pesticides or household products. These companies are referred to as the "product sponsors."

Thus, the confidential data to be protected could be the property of the contract laboratory, the product sponsor or both. For purposes of our illustration we assume that the confidential data is the property of the product sponsor. The product could be anywhere from a new chemotherapy drug to a new more efficient medical device.

It is possible, and in some cases, certain, that an inspection of the use of laboratory animals in a particular research or testing procedure would reveal the nature of the device or compound being tested. If it isn't obvious to the eye, then the answers to the question, "Why this procedure?" would be revealing because the particular use of the animal would derive from the product being tested.

The "Non-Associated" Committee Member. The Bill provides for the establishment of an Animal Research Committee, one member of which would be appointed from candidates outside the research facility. Specifically, section (3)(A) would provide that "... (1) at least one member shall have no association with such facility and shall be responsible for representing community concerns;..."

We do not imply that the "community member" intentionally would publish the proprietary data observed during the course of an inspection. But we do believe that observation is possible and in some cases inevitable. The problems are these: (1) what constitutes the proprietary importance of a piece of information may not be apparent to one not steeped in its technical nuances nor familiar with the product's development or its planned marketing in a highly competitive commercial environment; and, (2) the magnitude of research investment in the product or device and the dependency of recovery of investment on its successful marketing may represent a price tag not evident in the observance of the product or device.

The product sponsor may not feel justified in taking the risk of exposure to an individual with no contractual responsibility for the protection of the confidential data. The contract laboratory, therefore, may be faced with the unhappy choice of foregoing the federal funding, if it exists, or foregoing the contract.

We do not believe that it was intended to create that kind of choice situation - one that could have a profound effect of the economy of the contract testing industry.

The Anomalous Position of the Community Member

Looking at the appointment from the committee member's point of view, there are certain anomalies to contend with.

We assume that, especially in the Washington area, a community member with the necessary credentials could be found. The Bill specifies that the members must have "...sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility...1/

The question is whether an individual offering those credentials would desire to serve on the Animal Research Committee.

As a "non-associate" member the individual would probably enjoy the status of a visitor.

In a contract of employment or consultation there are reciprocal rights and duties spelled out in the contract between the laboratory and the individual, including, usually, the risk and liabilities inherent in the nature of the laboratory's testing mission. It isn't clear that the community member would enjoy this relationship.

It is the nature of toxicology testing that the toxic effects of chemicals or devices be observed. Not infrequently the effects observed are determined to be carcinogenic. Because of these risks of exposure, many laboratories may consider it appropriate to require that the non-employee execute written waivers of liability, holding the laboratory harmless.

The laboratory management might also consider it fair to remind the member of the sanctions for compromise of confidential data - either willfully or unintentionally - consisting of fines or imprisonment or both.

1/ If a qualified individual who would be willing to serve could not be found, the remainder of the Bills' provisions for inspection and reporting are placed in jeopardy. No alternative is provided.

In addition, the community member could be exposed to litigation for damages that might far exceed the member's personal resources.

If, in the Committee's judgement, it is necessary for the achievement of the Bill's objectives to mandate the appointment of a non-associated, community member, we recommend that the anomalies discussed above be studied carefully.

Be we do not believe that such an appointment is essential to achieve the objectives of the Bill.

The inspectors of the Animal and Plant Health Inspection Service of the Department of Agriculture are eminently qualified to perform the required inspections of the standards which the Bill would require the Secretary of Agriculture to promulgate.

NALSI would be pleased to work with the committee members and its staff in performing whatever additional research on the Bill may be indicated or in modifying portions of the Bill as the committee deems appropriate.

Thank you.

Howard C. Brown, Jr.,
Vice-President, Executive Director

Attachment "A"

Entities Presently Monitoring Research Animal Programs at Contract
Testing Laboratories

Government Monitoring

- United States Department of Agriculture/Animal and Plant Health
Inspection Service/Veterinary Services - USDA/APHIS/VS are responsible for enforcement of the Animal Welfare Act (P.L. 89-544) as amended 1970 (P.L. 91-579) and 1976 (P.L. 94-279). Areas of monitoring are transportation, purchase, sale, housing, care, handling and treatment of research animals. Monitoring accomplished by site inspections and by submission of various reports by the contract testing facility.
- Department of Health and Human Services

Each of the National Institutes of Health may monitor research animal care programs of recipient institutions by way of site inspection, protocol review or program review. These institutes may further

control the research animal care program by specifying program requirements in requests for proposals and/or the contract or award given. Additionally, institutional animal care committees are required by NIH through the Public Health Service. This committee is charged with protocol review and first hand monitoring of the institution's animal care facilities and animal care program.

In addition, the Public Health Service, Centers for Disease Control, Center for Prevention Services, Division of Quarantine monitors, through required quarterly or annual reports, those institutions which import non-human primates for research purposes.

- Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) through site inspections for compliance with their respective Good Laboratory Practice Regulation have the opportunity to monitor laboratory animal programs during such inspections. These agencies may invalidate studies submitted in support test agents if warranted by a poor program of laboratory animal care. Alternatively, through agreements between EPA, FDA and USDA, agency site inspectors may report adverse findings which are not in compliance with Animal Welfare Regulations (10 CFR) to USDA for investigation and action.

Voluntary External Monitoring

The American Association for Accreditation of Laboratory Animal Care (AAALAC) is a long established not for profit entity established by a number of well recognized trade, academic and scientific associations. One of the major functions of AAALAC is the thorough review of laboratory animal care programs of those institutions who seek accreditation.

Accreditation is based largely on the subject institutions compliance with the NIH Guide for Care and Use of Laboratory Animals, the Animal Welfare Act and other appropriate guidelines, regulations or laws. AAALAC inspections are conducted by AAALAC Council members and/or AAALAC consultants all of whom are qualified professionals in laboratory animal medicine.

Another institution which conducts accrediting site inspections is the Toxicology Laboratory Accreditation Board (TLAB) which inspects toxicology laboratories for their ability to adequately conduct various types of toxicologic testing. This is not a GLP type inspection, though this is included, but rather addresses the professional staff's capabilities and performance in individual technical areas. Specific test procedures are reviewed and evaluated. Accreditation is for specific procedures and not for the laboratories as a whole. One of the major areas of review is the toxicology laboratory's animal care program which is a critical element of safety testing. Each TLAB inspection team has among its members at least one professional qualified to determine the adequacy of the animal care program.

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Testimony of

**Marc H. Rosenberg, Executive Director
 National Coalition for Science and Technology**

Concerning H.R. 5725

Amendments to the Animal Welfare Act

**Before the Subcommittee on Research,
 Committee on Agriculture,
 U.S. House of Representatives**

Washington, D.C. - September 19, 1984

Mr. Chairman, my name is Marc H. Rosenberg. I am the executive director of the National Coalition for Science and Technology.

Our membership includes approximately 1,000 research scientists, educators, business people and engineers. We also count a number of corporations and professional societies among our members. The subject of animal research is of keen interest to many of the people and organizations we represent.

The use of animals in basic or applied research is a controversial topic, as you are well aware, and we commend this panel for holding today's hearing. The National Coalition for Science and Technology believes it is useful to have a public forum for a continuation of the dialogue between those who do animal research and those who are involved in the animal welfare movement. There are, on each side of this issue, people who take extreme positions, but there also are those who seek more reasoned alternatives to the existing laws and regulations.

For several reasons, Mr. Chairman, NCST does not support passage of H.R. 5725 or any other "animal welfare" legislation in these closing days of the 98th Congress.

As you know, there is a comprehensive study presently being conducted by the Office of Technology Assessment. The OTA has formed a number of panels consisting of animal welfare advocates, research administrators, distinguished scientists and concerned citizens to examine a broad range of issues pertinent to the use of animals in research. They are expected to report their findings in 1985. NCST believes the Congress should have the benefit of that detailed study before new legislation is enacted.

Moreover, there really is not enough time left in this session of Congress to resolve the broad philosophical divisions which currently exist. That is exactly why we feel today's discussion is a helpful interim step.

In fact, earlier this year, NCST itself sponsored a national forum on the use of animals in research and testing. We had participants from the academic and corporate research communities, animal welfare organizations, and several different governmental units.

After a full day of presentations and workshops, there emerged a consensus that more could be done to reduce duplication of animal research, to reduce the number of animals used in certain testing, and to improve dissemination of information about alternative methods of research and testing. The relative ease with which this consensus emerged leaves us optimistic about the outcome of a responsible and reasoned public dialogue on this subject.

One of the issues to be addressed today is whether the existing provisions of the Animal Welfare Act are adequate. The OTA report should help answer this question.

Regardless, we are aware that there are many people in this country who question whether animals in laboratories are adequately protected by the law. In several areas of the country, including the chairman's home state of California, concern over the care of animals used in research has jeopardized public support for certain health-related research programs.

With respect to the specifics of H.R. 5725, the proposed amendments to the Animal Welfare Act include several constructive ideas, but there are some features which need further work. NCST is prepared to cooperate with the chairman and this committee to help revise this legislation in anticipation of the activity that will occur after the OTA report is presented next year.

Today, we will focus our comments on five specific provisions of the pending legislation.

First, there is the requirement that laboratories using animals establish local review committees which shall include veterinarians and persons from outside the institutions. This roughly parallels proposals that have been made for monitoring animal research funded by the National Institutes of Health. While this proposal seems reasonable, we do have several concerns we wish to express.

In particular, we are worried that each local review committee would be permitted to establish its own standards and values concerning how animals should be treated. As a result, we could end up with a hodge podge of inconsistent requirements, with a particular practice being deemed acceptable in one place and prohibited in another. As we are talking about federally funded research or government-mandated testing, before these local review committees are established, we should have some agreement as to what standards are to be applied.

Similarly, we question whether work on a federally sponsored, peer-reviewed research project involving animals should be subject to yet another veto by a local review committee. At the very least, there should be a definite and swift appeals process that would provide the researchers recourse in the event of an over-zealous local panel which strays from the national norms.

Second, there is the provision that members of a local review panel must agree to the protection of any trade secrets or proprietary data which might be revealed in the course of a review. This provision is a marked improvement over other proposals we have seen.

Third, there is the proposal to create a voluntary national clearing house for information concerning animal research and alternative methods of research and testing. Such a clearing house would be useful, and we support it in concept. Again, though, we wish to express some reservations.

Creation of the proposed information clearing house will require the expenditure of some money, either new or reprogrammed. Even if the clearing house is placed within the National Agricultural Library, it will either require a separate line item in the budget or an explicit reprogramming of funds already available for other purposes. Perhaps H.R. 5725 is not the appropriate vehicle, but such language is necessary in either authorizing or appropriating legislation.

Additionally, we suspect that stronger language would be necessary to assure full cooperation and interaction with the National Library of Medicine. As so much animal research and testing is supported by the Department of Health and Human Services, that agency must be fully involved along with the Department of Agriculture in any data bank development.

Fourth, there is the requirement that institutions using animals for research and testing must annually provide their personnel with information and training relevant to the humane treatment of laboratory animals, including a review of the national voluntary data base. The intention is laudable, but there are some problems here as well.

In particular, NCST thinks that it is unrealistic to expect that smaller facilities could provide such training in any but the most cursory fashion. And for large facilities, it could create administrative and financial burdens.

Therefore, we suggest considering accepting inclusion of this information in continuing education or periodic recertification requirements of the principal investigators or professional staff at the facilities. Additionally, if such courses and training are required, then we should consider what assistance the federal government can provide in meeting this new obligation.

Fifth, there are some specific rules set forth for surgical procedures involving animals. At the risk of sounding as if we are contradicting our previous statement, NCST recommends that these be removed from the bill. Instead of setting these rules of surgical procedure in the statute, we think it would be more appropriate and pragmatic to leave the setting of standards of care to the regulatory process, with ample opportunity for public comment.

As an example of the kind of difficulty we seek to avoid, let me mention briefly the proposed ban on conducting more than one major operation on any one animal. While this may sound like a good idea on the face of it, the fact is that some medical research requires performing repeated surgery on the same subject.

This is often the case, for example, in research on brain and spinal cord injuries, where additional surgical intervention and subsequent anatomical analysis is essential to evaluate the course of medical treatments which could promote nerve repair. Such research would be prohibited by the proposed amendments.

Certainly, every reasonable effort should be made to assure that research animals are treated as carefully as possible, but flatly prohibiting specific procedures by law always runs the risk of casting the net too broadly.

In summary, Mr. Chairman, I again stress that the National Coalition for Science and Technology applauds your efforts to promote rational dialogue on this subject. We believe that today's hearing helps to pave the way for substantive legislative progress next year, and we stand ready to help you develop legislation which would assure the public that laboratory animals are indeed being treated humanely while this nation's researchers are permitted to make further progress in protecting and improving the health and well being of our citizens.

STATEMENT OF THE AMERICAN FARM BUREAU FEDERATION
BEFORE THE DEPARTMENT OPERATIONS, RESEARCH, AND
FOREIGN AGRICULTURE SUBCOMMITTEE OF THE
HOUSE AGRICULTURE COMMITTEE
REGARDING H.R. 5725, A BILL TO AMEND THE ANIMAL WELFARE ACT

Presented by
Stuart E. Proctor, Jr., Assistant Director
National Affairs Division

September 19, 1984

The American Farm Bureau Federation is the nation's largest voluntary general farm organization with over 3.2 million member families in 48 states and Puerto Rico. We appreciate the opportunity to present our position on legislation affecting the treatment of laboratory animals.

Our members are interested in the humane treatment of all animals because man is served by all animals. Farmers have the enviable reputation of being compassionate stewards of their livestock. But, despite our documented concern for the treatment of animals we are currently under attack from a number of associations and individuals who make inaccurate and misleading statements about the treatment of farm animals. Their intent is to make major reforms in livestock production practices in this country using emotional arguments, examples and generalizations to fabricate a problem where one does not exist.

We are concerned that some of these same tactics are being used to describe the treatment of laboratory animals. We question whether Congress has been presented with sufficient evidence to substantiate the need for corrective legislation. Congressional action to legislate and regulate in this area is inappropriate unless evidence is presented which shows a problem. Without such evidence Congress is being asked to overreact to an undocumented problem. We must remember that animal research is being conducted for the benefit of mankind. Unnecessary laws and regulations which could obstruct this research must be avoided.

To provide the data necessary to make legislative decisions concerning the regulation of laboratory animals, Farm Bureau supports the National Academy of Science study outlined in H.R. 2350 which passed the House. Legislative action is premature without thoroughly assessing how animals are currently being used in research. This study will provide an independent evaluation of this issue in a short period of time.

The study will help:

- Determine the type and number of animals used in such research;

- Review Federal and State laws and regulations governing the use of live animals in research. Evaluate the effectiveness of regulatory enforcement. Quantify enforcement problems by type and number;
- Evaluate the extent to which accrediting laboratories and research facilities protect animals against inhumane treatment;
- Analyze whether the use of animals is decreasing or increasing;
- Evaluate the actions taken by the National Institutes of Health to improve oversight of the use of live animal research;
- Assess the impact of establishing a requirement that research facilities be accredited; and
- Estimate the cost of equipping and modernizing research facilities to meet accreditation standards.

Farm Bureau will not support H.R. 5725 or other legislation on this issue until these basic questions are addressed. Answers to these questions will help determine the need for a legislative solution to the problem. If legislation is necessary, it should be targeted at specific problem areas and minimize any possible adverse affect on research being done for the benefit of mankind.

We feel that problems associated with the treatment of laboratory animals could be better handled with more diligent enforcement of current regulations. Last year the Committee on Appropriations asked for a GAO report on enforcement of the Animal Welfare Act. This year the Senate Appropriations Committee reports that GAO is about to issue a report which is very critical of APHIS's enforcement of this Act. Current regulations should be properly implemented before additional legislation is passed. If current regulations are ineffectively administered why will additional legislation and regulation be any more effectively carried out?

Congress and the Administration have given low priority to enforcement of the Animal Welfare Act by steadily reducing APHIS's budget. It seems inconsistent for Congress now to say this is a high priority issue which needs additional attention. If there is a problem, APHIS should be given enough funds to properly enforce the Act.

In view of efforts by farm and laboratory animal welfare activists to seek legislation for emotional reasons, we are also concerned there will be future attempts to apply animal welfare regulations to agricultural research. Therefore, it is important that the problem be accurately documented before legislative action is taken.

SCIENTISTS GROUP FOR REFORM OF ANIMAL EXPERIMENTATION

147-G1 THIRD AVENUE

WHITESTONE, NEW YORK 11357

(212) 767-0670

Statement of Dr. Herbert Rackow

On behalf of the Scientists Group for Reform of Animal Experimentation
for the hearings of the
Subcommittee on Department Operations, Research & Foreign Agriculture
Agriculture Committee of the House of Representatives
September 19, 1984

My name is Herbert Rackow. I am a retired physician, Diplomate of the American Board of Anesthesiology, Professor Emeritus of the College of Physicians and Surgeons, Columbia University, and a Fellow of the American Academy of Pediatrics. My professional career was at the College of Physicians and Surgeons, Columbia University, and at the Babies Hospital of the Columbia Presbyterian Medical Center. I was full time and did both clinical practice and research. My statement is on behalf of the Scientists Group for Reform of Animal Experimentation and is in favor of prompt enactment of H.R. 5725.

Representatives of the scientific community and those who supply their experimental animals have always raised objections to any proposed regulatory changes designed to ensure more humane treatment of laboratory animals and the development of alternatives to animal use. These objections were on the grounds that any new regulatory changes would be

- 1) extremely expensive
- 2) would stop medical progress and biological research
- 3) were unnecessary because laboratory animals are treated humanely.

The expense can not be prohibitive. Many European countries, not nearly as well off as the United States, are able to provide for humane treatment of laboratory animals. Furthermore, their treatment of laboratory animals is far more humane than is ours in the United States, and their humane regulations are more strictly enforced than are our own regulations.

Humane treatment of laboratory animals would not stop medical

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progress. The humane treatment of laboratory animals in these European democracies has not prevented their scientists from winning Nobel prizes. Some of our best young scientists go to their laboratories to complete their training. Many of our senior scientists go to these countries to spend their sabbatical years. The humane treatment of experimental animals has not brought their medical progress or biological research to a halt.

The proposed changes which H.R. 5725 provides, are necessary. For example, there was strong evidence in the Taub case, of inhumane treatment of monkeys. The evidence resulted in a conviction in two courts in Maryland. The evidence was confirmed by the National Institutes of Health. The fact that the two courts were later found not to have jurisdiction, in no way changes the evidence of inhumane treatment. It just makes Taub not legally guilty. The evidence also demonstrates that in this instance, the National Institutes of Health and the United States Department of Agriculture were incapable of monitoring and enforcing their own regulations for humane treatment of experimental animals. The changes as provided for in H.R. 5725 are in fact necessary.

Bill H.R. 5725 is designed to ensure humane treatment of laboratory animals, but its provisions are also valuable from a scientific standpoint. If experimental results in animals are to apply to man, it seems reasonable that conditions of ambulation, daily exercise, pre and post-surgical medical and nursing care similar to that provided for man, but appropriate for animals, be provided for the laboratory animal. The provisions of H.R. 5725 for exercise (page 4, line 4) and for pre and post-surgical medical and nursing care, would help ensure more humane treatment of caged and surgically treated animals. These provisions would also upgrade the standards of scientific methodology. There is recent evidence that exercise improves the quality of life and longevity in man. Exercise is even more important for the experimental dog who spends almost all of his restricted life in a laboratory cage that is just large enough for him to lie down in. No surgeon would treat a patient this way, by putting a healthy, vigorous person (healthy except for the local pathology requiring surgery) in bed for a few weeks before surgery and then after surgery, restricting the patient to bed rest for a few months. Because we know the value of early ambulation, even elderly patients are taken out of bed as soon as possible, often on

the first day post-op, if only to sit in a chair. Yet, experimental dogs are confined to cages for long periods of time. NIH Guidelines state that short term confinement to cages is one to three months. The provision for exercise might be expended in report language, to require daily exercise outside the cage, to provide for the physical and emotional well being of the laboratory dog. Socialization with other suitable dogs should be a part of the exercise period outside the cage. The exceptions that are already provided for in the bill (page 4, line 5) should be limited to the dog that is physically unable to exercise or because of scientific necessity as specified in the research protocol.

To ensure that animal pain and distress are minimized, the bill provides that the Secretary promulgate standards (page 4, line 12) for research facilities. The bill clearly states that the Secretary is not authorized to regulate the design of the actual research (page 4, line 8). Since the authority of the Secretary to promulgate standards is strictly limited, it is hard to understand any objections to this provision. Progress in medicine and the biological sciences does not depend upon the infliction of unnecessary pain and distress in experimental animals. This provision is important: it addresses a legitimate concern and has proper safeguards. It should be retained as written.

In the same way, the Animal Research Committee (page 6, line 11) is authorized to inspect the research facility (page 7, lines 7-14) for standards of animal care and for the condition of the research animals. As in the case of the Secretary, this committee has no authority to evaluate scientific aspects of the research. The provision for a minority report (page 7, line 24) is necessary to ensure that all views of the committee are recorded. All these provisions should be retained as written.

The need for an Animal Research Committee is very well described in Whistleblowing in Biomedical Research, 1981.* This study was sponsored by three groups: the Presidents Commission for the Study of Ethical

* Superintendent of Documents, US Government Printing Office, Washington, DC

Problems in Medicine and Biological Research, by the American Association for the Advancement of Science, and by Medicine in the Public Interest. It points out (page 35) that scientists in a university setting are under pressure to produce results and justify more money for more research. Promotion, tenure, salary, laboratory space and help, travel and other professional requisites depend upon research productivity. There is a strong conflict of interest that may affect even the best of persons. The university system of governance grants almost complete autonomy to departments and individual scientists. This may result in inadequate protection for human research subjects. If these considerations concerning research on human subjects, are valid, then the need for protection is even greater when the subjects are animals.

A provision has been made in the bill (page 8, line 9) that the Committee report unacceptable conditions to the administrative representative of the research facility. This should be expanded in report language, that the Director of Animal Care, in addition, be informed promptly of unacceptable conditions so that there is a minimum of delay in taking any needed action.

Similarly, if an employee reports a violation to the Animal Research Committee (page 9, line 13) , the Director of Animal Care should be informed of the violation immediately. The Director of Animal Care is likely to oversee animal care on a daily basis, while the Animal Research Committee is not.

The provision for annual sessions for instruction (page 8, line 22) in:

- A) the humane practise of animal maintenance and experimentation
- B) research or testing methods that minimize or eliminate the use of animals or limit pain or distress
- C) utilization of the information service at the National Agricultural Library, to prevent unintended or unnecessary duplication of animal experimentation

should include mandatory attendance by the scientists or their representatives and by those involved in the actual care of the experimental animals.

This provision should not only reduce unnecessary animal suffering but also should reduce the financial cost of biomedical experimentation without interfering with the progress of science. It should be retained.

The provision for the establishment of an information service at the National Agricultural Library, in cooperation with the National Library of Medicine (page 9, line 19), to provide information on improved methods of animal experimentation, to reduce or replace animal use, minimize pain or distress, and prevent unintended duplication of animal experimentation, is excellent and should be enacted as written.

The assurance of compliance provision (page 4, lines 15-24; page 6, lines 1-3) and the provision for suspension or revoking of Federal support for non-compliance (page 10, lines 6-11) are excellent and should be retained as written.

The provision that any State or political subdivision of any State may promulgate standards (page 6, line 4) is extremely important. I suggest that this be expanded in report language to ensure that each research facility with Federal funding must also be in compliance with laws of its own State and all political subdivisions of that State, as well as with Federal Laws. This will permit each of the States to experiment with its own standards. Those experimental standards that turn out to be of value, may in time be adopted by the other States.

The establishment of an effective Animal Research Committee is a key provision of H.R. 5725. We know from past experience that NIH site inspections and USDA inspections can be inadequate to ensure humane treatment of laboratory animals. In what way will the Animal Research Committee inspections be different ? The crucial difference is that for the first time, H.R. 5725 brings to the inspection committee (page 6, line 21), an independent, unpaid lay member, who is not affiliated with the research facility, has no conflict of interest, and whose primary responsibility is to the welfare of the animal subjects, not to NIH and not to the USDA. The effectiveness of H.R. 5725 in ensuring humane treatment of research animals,

will stand or fall on the quality of this member of the Animal Research Committee. I suggest that the qualifications of this person be listed in report language, to include that the person has demonstrated an active interest in animal welfare over a period of years , and has no conflict of interest in representing community concern for the welfare of animal subjects.

Thank you for the opportunity to make this statement in support of H.R. 5725.

THE FUND FOR ANIMALS INC.

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Edward Walsh, Jr.
Legal Counsel

TESTIMONY FROM GRETCHEN WYLER, VICE CHAIRMAN, THE FUND FOR ANIMALS
ON H.R. 5725

19 SEPTEMBER 1984

BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH AND FOREIGN AGRICULTURE
U. S. HOUSE OF REPRESENTATIVES

MY NAME IS GRETCHEN WYLER AND I AM VICE CHAIRMAN OF THE 250,000-MEMBER FUND FOR ANIMALS. OUR ORGANIZATION SUPPORTS H.R. 5725. THIS ACT ASKS FOR SO LITTLE - EXERCISE FOR DOGS, IN-HOUSE ANIMAL CARE COMMITTEES, RESTRICTIONS ON MULTIPLE SURVIVAL SURGERIES, MANDATED PRE- AND POST-OPERATIVE SURGICAL CARE, AND MEANS TO FIND LIVE ANIMAL ALTERNATIVES AND TO REDUCE DUPLICATION OF EXPERIMENTS. MANY PEOPLE WITH WHOM I'VE SPOKEN, INCLUDING OUR OWN MEMBERS AND PEOPLE FROM THE MEDIA, ARE ASTOUNDED THAT SUCH SIMPLE REQUIREMENTS ARE NOT ALREADY THE LAW OF OUR LAND!

DEFICIENCIES IN CURRENT FEDERAL REGULATIONS ARE IN STARK CONTRAST WITH THE FALSE REASSURANCES HISTORICALLY HEARD FROM THE RESEARCH COMMUNITY. BUT TODAY, EVEN THE MOST CONSERVATIVE ANIMAL RESEARCH LOBBY GROUPS ADMIT THAT THE CURRENT ANIMAL WELFARE ACT AND ITS ENFORCEMENT ARE GROSSLY DEFICIENT. FOR EXAMPLE, ON JANUARY 31, 1984, IN AN ILLINOIS SPEECH TO THE MEDICAL COMMUNITY, MS. FRANKI TRULL, EXECUTIVE DIRECTOR OF THE FOUNDATION FOR BIOMEDICAL RESEARCH, SAID THAT ONE REASON THE ANIMAL WELFARE ACT HASN'T WORKED WELL IS BECAUSE THE APHIS INSPECTION PROGRAM RECEIVES ONLY 4.8 MILLION A YEAR. TO QUOTE MS. TRULL: "LET'S FACE IT, THAT'S AN ABSOLUTE DROP IN THE BUCKET AND, OF COURSE, THEY THEREFORE HAVE INSPECTORS WHO ARE NOT TRAINED UNDER THE SAME TRAINING PROGRAM, WHO ARE NOT NECESSARILY QUALIFIED TO BE IN A RESEARCH INSTITUTION...I MEAN, WE'VE GOT A REAL PROBLEM." END OF QUOTE - FROM THE RESEARCH LOBBY.

ONE AREA OF GREAT CONCERN TO US IS PSYCHOLOGICAL RESEARCH WITH ANIMALS. I AM SUBMITTING DOCUMENTATION FROM DR. MICHAEL GIANNELLI, A MEMBER OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION AND SCIENCE ADVISOR TO OUR ORGANIZATION. HIS COMPREHENSIVE SURVEY OF 1984 ANIMAL RESEARCH PUBLISHED IN APA JOURNALS RAISES REASONABLE QUESTIONS ABOUT THE NECESSITY OF MUCH PUBLISHED WORK, AND REMOVES ALL REASONABLE DOUBT THAT ANIMALS ARE ROUTINELY MADE TO BEAR SUFFERING AND DESPAIR.

THE FUND FOR ANIMALS SUPPORTS THIS BILL, NOT BECAUSE IT WILL PROVIDE A MIRACLE CURE FOR ALL THE RESEARCH INDUSTRY'S ILLS, BUT BECAUSE IT IS AN ACHIEVABLE BILL AND A STEP IN THE RIGHT DIRECTION.

IN THAT SPIRIT, I AM PROUD TO SUBMIT A LIST (STILL IN FORMATION) OF SIGNED SUPPORT STATEMENTS FROM 44 PHYSICIANS AND VETERINARIANS FROM THE AUTHOR'S STATE OF CALIFORNIA.

WITH OUR COUNTRY'S NEW FOCUS ON FAIRNESS, HONESTY AND ETHICS IN THE "MARKETPLACE", THERE IS GROWING PUBLIC AWARENESS OF TAX WASTE AND ANIMAL ABUSE IN RESEARCH LABORATORIES. SINCE MOST RESEARCH IS PUBLICLY FUNDED, I URGE THIS COMMITTEE TO RECOMMEND PASSAGE OF H.R. 5725. IT IS AN OPPORTUNITY TO SHOW THE AMERICAN PUBLIC THAT CONGRESS CARES TO PROMOTE AND LEGISLATE HUMANE IDEALS.

CALIFORNIA PHYSICIANS AND VETERINARIANS
IN SUPPORT OF THE
IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT
H.R. 5725 (Brown) and S. 657 (Dole)

"As a member of the veterinary/medical profession, I am convinced that the legitimate needs of science are both compatible with and dependent upon the welfare of laboratory animals. Poor care and treatment of laboratory animals can lead to innaccurate or unreliable research data as well as unnecessary suffering by the animals themselves.

Current federal law needs to be strengthened in this area if these scientific and humane goals are to be met. H.R. 5725 and S. 657, the IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT, represent reasonable and moderate steps to increase assurances that humane care and treatment of laboratory animals are provided without restricting scientific freedom. For this reason, I wholeheartedly support H.R. 5725 and S. 657".

[List in formation and growing daily; current totals are:
28 MDs and 16 DVMs]

Gueri Axler, M.D.
Jeanne Axler, M.D.
Julia P. Bailey, M.D.
Patricia Bailey, M.D.
Richard P. Barrett, D.V.M.
Robert W. Bell, M.D.
Keith M. Berry, D.V.M.
Stephen Reeve Blake, Jr., D.V.M.
Richard S. Blinstrub, M.D.
Peter W. Bloch, D.V.M.
Wayne M. Comeau, D.V.M.
Gloria Dodd, D.V.M.
Donald E. Doyle, M.D.
Moneim A. Fadali, M.D.
William L. Farber, D.V.M.
Manuel A. Freitas, D.V.M.
Lawrence J. Friedman, M.D.
Jay N. Gordon, M.D.
David Griffiths, D.V.M.
Dennis R. Jurberg, D.V.M.
Harry B. Knaster, M.D.
Martin P. Koke, M.D.

Melvin M. Kotkin, M.D.
Terrance McGinnis, D.V.M.
Franklin D. McMillan, D.V.M.
Alan M. Mantell, M.D.
Alfred D. Munson, M.D.
Makram B. Masoud, D.V.M.
Eugene Natale, M.D.
John R. Oltman, D.V.M.
Chester Phillipson, M.D.
Constance Pinkerman, M.D.
Minton Ritter, M.D.
Steven Sanders, D.V.M.
Robert A. Shakman, M.D.
Daniel Silver, M.D.
James Stewart, M.D.
Helen S. Swank, M.D.
E. Douglas Tignor, D.V.M.
J. Robert Tolle, M.D.
Irma West, M.D.
Jacquelyn J. Wilson, M.D.
Stephen Winters, M.D.
James H. Yahr, M.D., F.A.C.S.

(The attachments are held in
the committee files.)

(List prepared 14 September 1984)

STATEMENT OF
THE AMERICAN FEED MANUFACTURERS ASSOCIATION
ON H.R. 5725
"IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT"

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH & FOREIGN AGRICULTURE
HOUSE COMMITTEE ON AGRICULTURE
SEPTEMBER 19, 1984

Steven L. Kopperud
Legislative Director

Chairman Brown, members of the subcommittee, I am Steve Kopperud, legislative director of the American Feed Manufacturers Association. On behalf of AFMA, I wish to thank the subcommittee for giving us this opportunity to comment on the Chairman's bill, H.R. 5725, the "Improved Standards for Laboratory Animals Act."

For over 75 years, AFMA has been the national trade association representing the nation's feed manufacturers. Members of the Association produce more than 70% of the primary formula livestock and poultry feed sold annually in the U.S. In addition, some AFMA members raise large numbers of food producing animals.

AFMA is proud of its long standing commitment to the proper treatment of all animals. In September, 1981, the Association's Board of Directors formalized that commitment in an official policy statement on the welfare of animals, the essence of which is that "AFMA is committed to the humane and compassionate care of all animals." A copy of that statement is attached to these comments.

AFMA's role in the recent debate over the relative quality of laboratory animal care has been misinterpreted by some who support this legislation. AFMA is vitally concerned that animals used in biomedical and agricultural research be treated in accordance with the highest professional standards. However, AFMA is also concerned that Congress not act in a manner which might ultimately--and unintentionally--place

barriers in the path of vital biomedical research, or act precipitously or unnecessarily to correct wrongs which may not exist to the extent some contend.

Chairman Brown's public support for necessary animal research and his assurances that H.R. 5725 is in no way intended to halt the use of necessary research procedures using animals satisfies AFMA's concern over the intent of this bill. However, AFMA continues to be concerned with the need for this legislation, for two very basic reasons.

First, the emotional "horror stories" which purport to show widespread disregard among biomedical research facilities using animals in experimental procedures have not been verified. Midnight raids on university research facilities to "liberate" such animals may make for good newspaper copy, but they do not constitute definable abuse and inhumane treatment. Legislation based on such an emotional response rather than the facts of the matter is undesirable.

There needs to be a broad spectrum of issues independently examined before any legislative remedy is contemplated. The level of cooperation between USDA and other federal agencies concerned with lab animal research, such as NIH, needs to be examined. Any administrative impediments to USDA's ability to carry out the ANA must be identified and reasonable solutions found. The actual state of the art in alternative research methods needs to be established, realistically appraised and implemented where practical. This type of scrutiny will permit any potential legislation to address specific problem areas with specific solutions while protecting necessary biomedical research procedures.

AFMA supports House and Senate legislation to investigate current laboratory animal care standards as a method of discovering any actual inhumane treatment prior to taking congressional action to create a duplicative set of standards to be added to the current Animal Welfare Act.

More importantly, however, if remedial action is necessary to ensure the high level of laboratory animal care, then it is logical that the time, money and energy being expended on H.R. 5725 and other similar legislation would be more productively focused on raising the priority of the Animal Welfare Act and its enforcement within the Administration and the Congress. The AWA has not enjoyed its highest priority in recent years, either in Congress, which has either seen fit to freeze or cut appropriations, or by the Administration which has not requested an increase for money or manpower.

If the productive use of federal funds and meeting the public's concern for lab animal care are the goals of this bill, then vigorous pursuit of an administrative solution is the answer.

Based upon a legal review of current law, AFMA concludes that the Secretary of Agriculture currently has sufficient legal authority to implement all but one of the statutory requirements on the use and treatment of laboratory animals proposed by H.R. 5725

In writing the AWA, it is clear Congress intended the Secretary to have the broad authority necessary to carry out the purpose of the act, namely "to ensure that animals intended for use in research facilities...are provided humane care and treatment."

7 U.S.C. sections 2136, 2140 and 2143, give the Secretary the specific authority to prescribe rules and regulations for the registration of research facilities; establish recordkeeping and reporting requirements, and to promulgate humane standards for the use of laboratory animals.

This standard-making authority is the most significant and the most specific within the AWA. It details the parameters of those standards and the required demonstration by the research facility that it is following professionally acceptable standards for laboratory animal care and treatment. It also orders the Secretary to consult and cooperate with other federal agencies in setting and carrying out the standards and purposes of the AWA.

Let me discuss the major provisions of H.R. 5725 and the status of those proposals under the current AWA:

1. Annual compliance assurances by research facilities: H.R. 5725 would require yearly assurance by the research facility that it is in compliance with humane standards of animal care, especially in any practice involving the administration of pain to an unanesthetized animal. A proviso to Section 13(a) of the AWA, 7 U.S.C. ss: 2143(a) provides such authority:

-The Secretary shall require, at least annually, every research facility to show that professionally acceptable standards governing the care, treatment and use of animals, including the appropriate use of anesthetic, analgesic and tranquilizing drugs, during experimentation are being followed by the research facility during actual research or experimentation."

2. Animal Research Committees: Chairman Brown's bill would order the establishment of internal animal research committees by each research facility. Our review shows no difference between H.R. 5725 and current authority. Indeed, current regulations allow for the optional use of an animal research committee in lieu of or in addition to an attending veterinarian. It is apparent the Secretary was given the implied or inherent authority to require such panels. The precedent has been set by other agencies, i.e. FDA requires "institutional review boards" to be established by all entities seeking approval for new drugs and medical devices, a practice not expressly authorized under the Federal Food, Drug & Cosmetic Act.

3. Inspection Provisions: H.R. 5725 calls for the inspection results of the Animal Research Committee to be made available for review by USDA inspectors. The Secretary has the authority to conduct inspections to see if the facility has violated law, a regulation or standard under Sec. 16(a) 7 U.S.C. ss:2146(a). No new authority would be needed.

4. State or Local Standards: H.R. 5725 would not preempt the states' right to pass stricter regulations. The current AWA allows for state regulation (Sec. 15 of the AWA 7 U.S.C. ss: 2145(b)). This section allows the Secretary to cooperate with the states in carrying on the same subject."

It appears the only administrative change which cannot be made by the Secretary is to impose criminal penalties for release of trade secrets, an area very important to public and private research facilities. Under constitutional law, an administrative agency cannot impose a criminal penalty unless expressly authorized to do so by Con-

SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION

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STATEMENT IN SUPPORT OF H.R. 5725
 BEFORE THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
 RESEARCH, AND FOREIGN AGRICULTURE

September 19, 1984

by Christine Stevens, Secretary

Mr. Chairman, on behalf of the Society for Animal Protective Legislation, I wish to commend the reasoned approach and the long-term interest you have demonstrated in seeking to limit the suffering of laboratory animals. As one of the best friends of science in the Congress, your efforts should be crowned with success.

If H.R. 5725 is enacted into law, it will be helpful to research. The federal Animal Welfare Act, which it amends, now has the approval of the major biomedical research organizations as demonstrated by their endorsement of a two-thirds increase in appropriations to enforce the Act (1). Several of these organizations were at the forefront in fighting passage of the Act in 1966 and its amendments in 1970 and 76, but the fears they then expressed have proved to be groundless. The same will prove true with your bill, Mr. Chairman, if vested interests do not succeed in blocking its passage. The interests I refer to are not scientific; they are commercial and they foster illusory fears and play on prejudice to gain their selfish ends -ends as harmful to the scientific community as they are to the welfare of animals. Their rallying cry is: "Study!"; their aim: to delay, and, through delay, to defeat the urgently needed H.R. 5725. They portray needless animal suffering in laboratories as a rarity and want to pay the National Academy of Sciences to study the question at length.

Far from being a rarity, the data collected by the Animal Welfare Institute on enforcement of the Animal Welfare Act * shows major and repeated "deficiencies" or "alleged violations" of the minimum standards of the Animal Welfare Act by 23.7% of the sample of 186 institutions whose inspection reports and annual reports have so far been examined. Another 22% have less frequent major violations; 28.5% have only minor ones; 1.6% are under investigation; and the rest, according to the USDA veterinary inspectors'

*See Appendix A

The committee also took exception to the USDA's budgetary "assumption" that states, industry groups and others would take additional responsibility for enforcing the AWA, despite their lack of authority, and stressed that the Committee expects USDA's fiscal 1986 budget request will include sufficient funding to administer the AWA.

The logical route then is to seek administrative changes in the current implementation of the AWA. Biomedical research interests, agriculture and animal welfare interests can cooperate as a unit to achieve reasonable, mutually acceptable goals. This is preferable to a legislative tug-of-war, where the innocent victim may be necessary, vital research successes.

AFMA again thanks Chairman Brown and the subcommittee for this opportunity to comment on H.R. 5725.

SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION

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*See Appendix A

records are abiding by the, and I repeat, minimum standards. Even these cannot be assumed to be in regular compliance with the law because some USDA inspectors have been found to have overlooked serious violations in the past. Indeed USDA's Veterinary Services which administers the Act, has commendably instituted a policy of double checking on inspection reports which show few if any observations in order to ensure that compliance is as uniform as possible.

Thus, even using the most optimistic assumptions, only 24.2% of registered research facilities are regularly meeting the existing minimum standards of the Animal Welfare Act!

Reading the veterinary inspectors' reports has been an astonishing experience for me, for though I have visited many laboratories and observed much needless purposeless suffering which is counterproductive to scientific aims, I would not have guessed that so many renowned institutions were so oblivious to the duty (to which all give lip service) to treat laboratory animals decently, that they allow gross mistreatment to continue unabated or if corrected under prodding by USDA inspectors, to recur.

The attached listings specify the level of compliance of 186 institutions. The chart prepared for the 44 in Category I indicates whether or not the institution is accredited by the American Association for the Accreditation of Laboratory Animal Care, and you will note that many AAALAC-accredited facilities have major deficiencies, clearly demonstrating the National Institutes of Health, position that accreditation guarantees good animal care and treatment, to be untenable

The charts further indicate the level of NIH funding in two consecutive years, and the numbers of dogs cats, primates, rabbits, hamsters and guinea pigs used in those years. The number of animals used is higher in 40.9% of the 44 institutions in the second year, demonstrating that the glib and often repeated statement that the use of animals is just naturally decreasing and there is no need of legislative encouragement in this area to be far from accurate. It is noteworthy, too, that 79% of these severely deficient institutions were rewarded by an increase in NIH funds in the second year noted. Twenty-five percent of the 44 used more animals and got more money from NIH despite their bad record with USDA.

The chart's final column shows the numbers of animals reported by the institutions to have suffered pain or distress unrelieved by anesthetic, analgesic, or tranquilizing drugs. These are decidedly the least reliable of the figures given since the majority of institutions decline to admit, in filling out their annual reports that

even one animal suffered!* This curious fact is a measure of the urgent need for enactment of H.R. 5725. Whether the person who fills out an institution's annual report is deliberately misstating the amount of unrelieved animal suffering or is simply blind to it, matters little. The animals are needlessly suffering, and legislation is essential to prevent it.

Such legislation has been widely adopted by countries where laboratory animals are used extensively. Indeed, the only major exceptions to this general rule are Russia and Japan, countries in which animal protective legislation of any kind is almost non-existent. National pride alone should spur us to bring our standards up to those of the Western European democracies which have (and mainly have had for 20 years or more legislation aimed at pain-reduction for laboratory animals Austria, Belgium, Denmark, Federal Republic of Germany, France, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Sweden, Switzerland and the United Kingdom.

Scientific endeavor experienced no setbacks as the result of these laws. Scientists have never sought their repeal.

To illustrate the need for enactment of H.R. 5725 eight video sequences shot in six different institutions have been produced by the Society for Animal Protective Legislation from footage taken by the Lifeforce Foundation. We will be happy to show this three-minute tape to Members, staff and others who wish to view them. I include herewith a brief description of each example and the relevant provision of the bill.

VIDEO SEQUENCES ILLUSTRATING NEED FOR SEVEN DIFFERENT PROVISIONS OF H.R. 5725

All the laboratory animals in these sequences are alone and unattended.

1. This pup may injure itself on the dangerous piece of loose metal projecting from the much gnawed whelping box, an example of negligence which the bill's mandated Animal Research Committee, including a public member to represent community concerns for the welfare of the animal subjects, would correct in its semi-annual inspections.

*For example, the USDA veterinarian inspecting Washington University in St. Louis wrote 4/22/82, "A sick kitten was observed which was not under the care of a veterinarian [a deficiency in itself]. Blood from rectum and paresis of rear limb. No pain or distress report on file as prescribed by Section 2.28(4) of this regulation."

2. This dog, used in a bone fracture experiment, has chewed through the bandage and bitten his own skin. Although observed by the animal caretaker, no action to replace the dirty and half destroyed bandage has been taken. The bill requires post-operative care in accordance with established medical and nursing procedures.

3. This dog is suffering unbearable pain and bleeding heavily following heart surgery. Clearly the necessary analgesics have not been administered. The bill provides that pain-relieving drugs or euthanasia may not be unnecessarily withheld from suffering animals.

4. After having their eyelids sewn shut, these cats are disoriented. They are hungry and thirsty because their food and water bowls were not attached and thus were easily spilled. The cats are in great distress. The bill provides for laboratory personnel to report violations of the standards to the institutional committee and protects them from discrimination for such reporting.

5. Monkeys in restraining chairs may be kept there for weeks or months, though tethering devices which allow regulated administration of drugs can be substituted in many cases for monkey chairs. An Information Service at the National Agricultural Library in cooperation with the National Library of Medicine is provided in the bill to give information on improved methods of experimentation which could replace, unnecessarily stressful practices.

6. Picking at his wounds, with blood running down from the side of his head where the brain surgery and implanted electrodes leave his skull open, this monkey is in danger of developing major and possibly lethal infection. Veterinary consultation, as required by the bill, appears to be absent.

7. Primates are chained and a pole is used to force them into the restraint device. Fighting against his chain, this monkey may break his teeth. The bill provides for instruction in the humane practice of animal maintenance.

8. In a convulsion caused by the experiment but observed by no experimenter, this primate suffers without relief. The bill requires that in any practice involving pain to unanesthetized animals, a Doctor of Veterinary Medicine be consulted in the planning, and that withholding tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue no longer than necessary.

For anyone who 1) has a strong stomach and 2) is not convinced of the urgent need for enactment of H.R. 5725, I also recommend viewing videotapes taken by scientists of the University of Pennsylvania Head Injury Clinical Research

Center of themselves and their experimental subjects. Because the original tapes were stolen from the laboratory by a group called the Animal Liberation Front, copies are not being shown in the House of Representatives. People for the Ethical Treatment of Animals has a half-hour of excerpts from a copy of the 60-hour long tapes which can be viewed by all interested persons.

In looking at this half-hour, I noted numerous graphic illustrations of needless suffering which could have been prevented by the legislation. Selecting seven sequences, I wrote corresponding citations of the bill's provisions, and this material follows. The relevance to the bill is given in all capitals, the experimenters' remarks in lower case.

I should state that the Society for Animal Protective Legislation does not endorse the theft of the tapes. After consultation with counsel, we find that it is not illegal to show and view these copies of the incriminating evidence. Excerpts have already been widely viewed on television. We believe an examination of them will be of value to the Congress in understanding why there is such vehement and constantly increasing dissatisfaction with improper conduct of animal experimentation, as vividly documented in these tapes. And it is especially relevant to Congress since it shows so clearly the waste of government money.

Sequence I

THE HEAD INJURY CLINICAL RESEARCH CENTER OF THE UNIVERSITY OF PENNSYLVANIA RECEIVED NEARLY A MILLION DOLLARS FROM THE NATIONAL INSTITUTES OF HEALTH IN 1983.

THE BROWN BILL WOULD PREVENT DISCRIMINATION AGAINST PERSONNEL WHO REPORT ANIMAL MISTREATMENT TO THE INSTITUTION'S ANIMAL RESEARCH COMMITTEE SO THAT CORRECTIONS CAN BE MADE WITHOUT ADVERSE PUBLICITY.

THIS BABOON IS UNDERGOING SURGERY WITHOUT ADEQUATE ANESTHESIA. NOTE THE ANIMAL RAISING HIS TAIL. THIS IS CRUEL ON-THE-JOB LEARNING. NOTE ONE EXPERIMENTER HOLDING DOWN THE BABOON'S LEG.

*(a) Oh! He's lifting his head!

Come on, baby!

(b) I better get some nitrous. [nitrous oxide, an anesthetic agent]

(a) Stop! stop, for heaven's sake. He wants to get up. He says I've had it. It hurts him, for Christ's sake. All you got to do is make a little slit in the periosteum and and push it back.

(b) Ya, but it bleeds.

*Two experimenters talking are indicated by (a) and (b)

- (a) You got to do something to control the bleeding.
That's what the bovie is for...Not there, There!

THE BROWN BILL REQUIRES TRAINING SESSIONS FOR SCIENTISTS AND TECHNICIANS IN METHODS TO LIMIT ANIMAL PAIN AND DISTRESS. IT REQUIRES THE USE OF PAIN RELIEVING DRUGS TO MINIMIZE SUCH PAIN IT PROVIDES FOR AN INFORMATION SERVICE ON IMPROVED METHODS SUCH AS ANESTHETIC AND ANALGESIC PROCEDURES.

THE BROWN BILL REQUIRES THAT PAIN RELIEVING DRUGS NEVER BE WITHHELD LONGER THAN NECESSARY.

Sequence II

THIS BABOON IS ABOUT TO BE SUBJECTED TO HIS SECOND INJURY

(a) This is monkey B 9. The monkey now weighs 8.8 kilos. The animal is down for a second lateral bang. That's him waving. As you can see the monkey's awake, moving all extremities That s his trainer who's taught him how to do those tricks. The animal is mounted in a helmet. He is monitored for ICP, EKG, EEG, blood pressure etcetera. The animal is to be thrust in the lateral position to become a chronic animal, uh, for long term studies.

(b) You might want to mention the monkey's already been banged once.

(a) I said that, a second bang.

(b) Did you say that?

(a) This is his second bang. He was banged once at 680 g force and quickly recovered. Cheer leading over in the corner we have B 10. B 10 wishes his counterpart well. As you can see, B 10 is alive. B 10 is watching and hoping for a good result for future B 17 over here.

Sequence III

REMOVAL OF THE HELMET APPEARS TO BE AN OCCASION FOR MERRIMENT

(a) Change his name, and we'll call him "Slim." We could run a diet service, bring 'em in alam 'em, put 'em to bed. (hammering and laughter) Thibault's weight reduction clinic.

THE HELMET WHICH IS CEMENTED TO THE BABOON'S HEAD WITH DENTAL CEMENT IS BEING HAMMERED WITH A CARPENTER'S HAMMER AND SCREW DRIVER TO BREAK IT APART.

(a) We don't know where to put 'em. This guy's waking up. Conceivably we will come in and they'll be running around the lab. He's moving! He's moving! He has this

little string on his tail. We just pull. (more hammering) Push!
Ooh! It's a boy!

THIS CRUDE METHOD OF REMOVING THE HELMET CAUSES UNQUANTIFIED TRAUMA TO THE EXPERIMENTAL SUBJECT.

- (a) We're thinking of going on strike. The contract says no more than three comatose boonies at any one time. That's in the contract. (more hammering)
- (a) Seems like I left a little ear behind.
- (b) Oooohay!

THE BROWN BILL REQUIRES THE INSTITUTIONAL COMMITTEE TO BE NOTIFIED OF ANY CHANGES IN PRACTICES ADVERSELY AFFECTING THE WELFARE OF THE ANIMALS. USE OF HAMMER AND SCREWDRIWER WERE NOT MENTIONED IN THE GRANT REQUEST.

Sequence IV

RESEARCHERS, STANDING OVER ANOTHER BABOON ON THE OPERATING TABLE, DISCUSS THE LACK OF SANITATION

- (a) Why is it so dusty down here? Why, because they're basically incompetent down here. Well, I mean, just in general our procedures cause dust. They don't...They're not regular in cleaning at all, and I've called them three times. When they do clean they're half-ass. Lately the ventilation system has been spewing out some sort of...dust. It's the type of thing...Ya, I don't, you know. I complain about it, but you know.... When you come down here it smells like urine.
- (b) We have three months of urine down in the bottom of that thing...Urine asphyxiation...toxicity.
- (a) We had to get her out of that. She was just filling it up with buckets of urine.

THE BROWN BILL REQUIRES SEMI-ANNUAL INSPECTIONS BY AN ANIMAL RESEARCH COMMITTEE INCLUDING A VETERINARIAN AND AN OUTSIDE MEMBER RESPONSIBLE FOR REPRESENTING COMMUNITY CONCERNS FOR THE WELFARE OF THE ANIMAL SUBJECTS. UNCORRECTED DEFICIENCIES MUST BE REPORTED TO THE DEPARTMENT OF AGRICULTURE AND FUNDING AGENCIES.

Sequence V

WHILE CONDUCTING A SURGICAL PROCEDURE ON ANOTHER BABOON'S HEAD, THE EXPERIMENTER, WHO WEARS NO MASK, CAP OR STERILE CLOTHING, DROPS AN INSTRUMENT ON THE FLOOR, PICKS IT UP WITHOUT REMOVING HIS GLOVES AND WITHOUT STERILIZING IT, CONTINUES THE OPERATION. THE SURGEON IS SMOKING A PIPE. AN ASSISTANT IS SMOKING A CIGARETTE, AND A THIRD BENDS OVER THE UNDRAPED BABOON ON THE OPERATING

TABLE, HOLDING A CIGARETTE WITH A LONG ASH IN HIS MOUTH.

(more smoking)

THE BROWN BILL PROVIDES THAT A FEDERAL AGENCY SUSPEND OR REVOKE SUPPORT FOR A PROJECT IF ANIMAL CARE, TREATMENT OR PRACTICES HAVE NOT BEEN IN COMPLIANCE WITH APPLICABLE STANDARDS. THE NIH GUIDE WAS REPEATEDLY VIOLATED IN THIS NONSTERILE SURGERY.

Sequence VI

THE BROWN BILL REQUIRES THAT A VETERINARIAN BE CONSULTED IN THE PLANNING OF ANY PROCEDURE INVOLVING PAIN TO UNANESTHETIZED ANIMALS. NOTE THE BABOON PULLING AGAINST THE BONDS ON HIS LEGS AND SWITCHING HIS TAIL AS THE MACHINE ADMINISTERS THE POWERFUL FORCE.

Sequence VII

(a Come on, monkey, hang in there just a little longer, baby!

A DYING BABOON IS ATTENDED ONLY BY A STUDENT WHO CURSES "THE PROBLEM" BUT CANNOT DEAL WITH IT. THE BROWN BILL REQUIRES POST-SURGICAL CARE IN ACCORDANCE WITH ESTABLISHED MEDICAL AND NURSING PROCEDURES.

It is regrettable indeed that spokesmen for the University of Pennsylvania asserted publicly (2) that the baboons were anesthetized and felt no pain. These statements show remarkably poor judgment inasmuch as: 1) The videotape clearly shows a baboon undergoing head surgery with inadequate anesthesia (see above, "It hurts him for Christ's sake"); and 2) The NIH protocol (3) for the grant states that the general anesthetic is allowed to wear off for a full hour before the massive injury is inflicted. Line 1, page 193 of the grant application reads "Through the endotracheal tube the animal spontaneously ventilates 70-80% nitrous oxide anesthesia until 1 hour before acceleration after which it breathes room air."

To cap it all, the University of Pennsylvania claims in its annual report to the U. S. Department of Agriculture that it caused no unrelieved pain to animals!

As bad as the misrepresentation is, even more serious is the fact that scientific results obtained with that kind of mistreatment of animals can't be depended upon because of the way the experiments are carried out. Following are the figures for the past four years of grants from the National Institutes of Health to the Head Injury Clinical Research Center of the University of Pennsylvania: 1980, \$ 955,593; 1981, \$ 841,537; 1982, \$ 886,334; 1983, \$ 969,571.

Fine words can no longer convince the public that laboratory animals live pain-free lives. The scientific community would be wise to embrace the moderate bill, H.R. 5725, and encourage its thorough enforcement to prevent the needless animal pain and distress that dishonors otherwise reputable institutions.

Occasionally an opponent of the bill will attack the very concept of pain, alleging that it cannot be defined. A clear and useful definition made by Professor Patrick D. Wall states, "Pain in animals is manifested by abnormal behavior which can be alleviated by analgesic procedures which relieve pain in humans. The international journal *Pain* gives this definition of severe pain. "Severe pain in animals is pain produced by procedures to which normal humans would not voluntarily submit without appropriate analgesia or anesthesia." Dr. A. Lawrence Abel, former Vice President of the Royal College of Surgeons of England testified at Congressional hearings on laboratory animal legislation in 1965, "Fear is the psychological equivalent of pain." Both must be avoided to the greatest possible extent, psychological distress being as serious as physical pain.

I was interested to learn that "learned helplessness" experiments a state of pathological inability to act as a result of inescapable pain, have never been conducted in Britain, nor is there any indication that they were ever proposed. A review of the literature in other countries describes dogs subjected to intense inescapable electrical shock (including a series of 64 painful shocks in two hours while suspended in a harness) as follows: "They stopped running and sat or lay down quietly whining." The paper concludes that "This relatively simple hypothesis has been supplanted by a more complicated formulation" and that "Investigators of human helplessness . . . have become increasingly disenchanted with the adequacy of theoretical constructs originating in animal helplessness for understanding helplessness in humans." Nevertheless, we are told that "In the long run it is probably better to have compared and erred, than never to have compared at all." (From *Comparing Behavior: Studying Man Studying Animals*, edited by D. W. Rajecki (Lawrence Erlbaum Associates, Hillsdale, NJ, London, 1983).

The amount of pain and fear to which many dogs were subjected for the past 17 years only to find that investigators are "increasingly disenchanted" with the relevance of the results to humans, is not mentioned in the review of the subject.

Whether or not more humane alternatives were considered by one or more of the investigators cited is not possible to say. But it is of fundamental importance that such consideration be given by principal investigators when they

are developing their ideas. The provision in H.R. 5725 is mild. It simply requires that the principal investigator consider alternatives to any procedure likely to produce pain or distress in an experimental animal. The institution must provide an assurance demonstrating that he has done so.

Completely non-authoritarian, this provision would bring to fertile scientific brains the concept of humane planning of experiments. Asking a young experimental surgeon, who was showing me around a room containing horribly emaciated and cringing dogs, whether he tried to plan experiments humanely, he responded with obvious surprise, "I never thought of that."

If H.R. 5725 were law, the need to think before starting would be established.

H.R. 5725 would not prevent all pain to animals. Rather it would prevent avoidable pain and pain that can be relieved by drugs and other methods. The principal investigator would retain every privilege he now holds with respect to the design of his experiment. To comply with the law, he would consider alternatives to any painful experiment. The Information Service at the National Agricultural Library in cooperation with the National Library of Medicine would provide him with updated information on substitutes for laboratory animals, ways of limiting their numbers to those strictly necessary, and the best ways of preventing pain and distress. He would report to the institution's Animal Research Committee any changes in his work which would adversely affect the welfare of the animals. He would consult with a veterinarian before performing an experiment which could cause pain in order to ascertain the best methods of avoiding it. The semi-annual inspections by the committee would assist the U. S. Department of Agriculture in maintaining good standards.

This bill is the product of years of work, consulting representatives of scientific and animal welfare organizations. The process began in 1982 with a series of five four-hour long meetings including the American Physiological Society, American Psychological Association, Association of American Medical Colleges, National Society for Medical Research, Society for Animal Protective Legislation, Humane Society of the United States, American Humane Association and People for the Ethical Treatment of Animals, among others. The process continued resulting in S. 657 authored by Senator Robert Dole (R.KS) and, after hearings July 20, 1983, additional work based on testimony presented was undertaken. Many of the groups who asked for changes have expressed appreciation of new phraseology in H.R. 5725 yet still further suggestions continue to be made. I would like to take this opportunity to make two suggestions designed to increase scientific support for the bill.

Page 6, line 18 add "and shall concern themselves with the welfare of the animal subjects." This would give the scientific members a mandate on animal welfare supplementing the vitally important directive to the "outside" member who "shall be responsible for representing community concerns regarding the welfare of animal subjects." These 13 words are central to the effectiveness of the bill.

The National Institutes of Health's proposed principles (4) include an outside member, but they lack these essential words which are needed by the laboratory animals and the scientific community alike.

Until genuine efforts are made by all registered research facilities to put an end to the massive abuses and waste of funds in questionable research results obtained with neglected, diseased, suffering or otherwise unsuitable animal subjects, more and more damaging disclosures will continue to be made concerning the needless suffering of these animals. There is just one effective way to stop this rapidly growing trend: support H.R. 5725. Get it passed; and instruct all personnel to obey it, thus ensuring that laboratory animals are decently treated. Then the outside member charged with representing community concerns for the welfare of the animal subjects will be able to state honestly that the concerns have been met. The key 13 words, together with the pain preventing provisions supply the means to accomplish the goal which all concerned would like to see: an end to needless pain in animal laboratories.

The second suggestion is to move the sentence beginning "The Secretary" line 11, page 4 to follow line 4 on the same page. The purpose is to clarify the meaning. Further clarification could be achieved by re-ordering the words in the sentence (line 12) to read "promulgate research facility standards" rather than "standards for research facilities."

The U.S. Department of Agriculture objected at hearings on S. 657 to use of the adjective "proper" to modify the standards. In H.R. 5725 no adjective is used, but I understand that USDA wants to retain the word "minimum." This would be unwise because the word has been interpreted in a most deleterious way especially by dog dealers. To give an example, a dealer argued that because the standards are "minimum" it would be quite all right to use bits of old tires as watering vessels for the dogs. "Minimum" really means to everyone who wants to justify cutting corners that "anything goes." The word itself has contributed to the difficulty experienced in getting full enforcement of the Animal Welfare Act. We urge that it be dropped, as wisely done in H.R. 5725.

USDA also asks for guidance on the addition to the standards

of exercise for laboratory dogs. The basic intent is that where dogs are caged, they be released at least daily from their cages. Some institutions release them to an outside runway. Others simply let them run around the room while the cages are being cleaned. In some cases a hallway can be used as an exercise area or an inside pen can be used. If dogs are housed in pens or kennel runways they do not need to be moved at all. The Subcommittee may wish to include report language for the guidance of USDA in rule making on this matter.

As recognized by a growing number of research facilities, dogs evolved as pack animals running long distances to capture prey. A cage cannot even begin to meet this species' behavioral needs. The Animal Welfare Institute publishes a manual Comfortable Quarters for Laboratory Animals which is made available free on request to scientific institutions. It contains many different photographs of acceptable provision for housing dogs and other laboratory animals for the guidance of scientists and regulators alike.

USDA also questions the requirement that its veterinary inspectors visit the animal laboratories of other federal agencies to enforce the standards. We believe this would have a highly beneficial result, because although the existing law requires all agencies to adhere to the standards established by the Secretary of Agriculture, there is no means of ensuring that this actually happens. This is the only part of the bill which would require any increased funding the cost of sending representatives of Veterinary Services to the different sites. In our opinion this would be well worth the expenditure. We urge retention of the provision.

OPPONENTS WITH A VESTED INTEREST

The Association for Biomedical Research is a trade organization, founded by Charles River Breeding Laboratories, a multi-national, multi-million dollar business which recently become a part of Bausch and Lomb, the big optical company.

To give an idea of the size of the funds involved, I quote The Boston Globe, November 24, 1983: "Charles River had about \$45 million in sales during the last 12 months and earnings of \$6.2 million.... Bausch & Lomb, based in Rochester, NY, is nearly 13 times the size of Charles River.... Dr. Henry L. Foster, the founder and president of Charles River, owns 29 percent of the company's stock which would be worth about \$37.8 million if the deal goes through." It did.

How were these huge profits made? The answer is simple; by skillful and unrelenting promotion of the sale of the maximum

numbers of animals to scientific institutions. Even animals as small and inexpensive as white mice can turn a fat profit if they are produced by the tens of millions and marketed with full page ads in every issue of the right journals. Monkeys, of course, bring far higher prices, and Charles River trumpets their ready availability in ads which since Bausch and Lomb took the company over are not only full page but full color, too. "Don't put your research on hold," scientists are advised "Link up with a primate that means quality. Our cyno. Or any of our other 10 commonly used species."

Readers would never guess that all primates are either on Appendix I or II of the Convention on International Trade on Endangered Species of Wild Fauna and Flora (endangered, or threatened with extinction). Most are wild caught.

The more animals used, the larger the profits for Charles River/Bausch & Lomb. As founder of the biggest laboratory animal business in the world, Henry L. Foster was quoted in The Wall Street Transcript, 5/21/78, "...if you read the papers, everything seems to have carcinogenic effects. But that means more animal testing which means growth for Charles River. Just let me take a few more minutes to read you a list that rather excites us....All these companies are building [testing facilities]. So you can see why we continue to be enthused and excited."

In the course of developing even more massive animal sales worldwide, Charles River boasts "a triumph for good breeding" of its animals, but when The New York Times (5) reported that about 1,000 experiments had been thrown off when Charles River's BALB/c mice turned out to have been genetically contaminated the company barely turned a whisker. A lawsuit by cancer researcher Brenda Kahan, of the University of Wisconsin, charged that Charles River "deliberately did not notify its customers" or failed to perform the necessary tests was settled out of court, and the question asked by Alvin Warfel (6) "If they can't guarantee they're selling BALB/c mice when they say they are, why are they in business?" was never answered.

The National Institutes of Health is a big and steady customer of Charles River. In 1983 alone NIH had eight contracts with the company for a total of \$3,571,407. The Science article, "Scientist Sues Over Genetically Impure Mice," raised more questions than it answered about NIH's role. Certainly there were no alarm signals sent out by NIH that were loud or clear enough to alert Dr. Kahan that she had the wrong mice when she was conducting cancer research which depended on their genetic purity. Had there been, the wasted research, wasted government funds, and purposeless animal usage would have been prevented.

Frankie Trull, the Executive Director of the Foundation for Biomedical Research as well as the Association for Biomedical Research, works closely with NIH, organizing panels on which both the present and past directors of NIH appear, and, in turn, speaking on NIH panels.

ABR and NIH have worked hard to convince the Congress that H.R. 5725 and S. 657 should not be passed before an 18-month study is undertaken by the National Academy of Sciences and reported on - in other words until two more Congresses have run their course. This time-honored way of killing mandatory legislation was acknowledged by Ms. Trull in a presentation January 31 1984 at the Health Sciences Center of the University of Illinois, open to all faculty, staff, and students where she noted, "Now we are criticized for being strong proponents of study legislation by animal welfare organizations who say this is a stalling tactic. Well, I mean, you know, none of us was born yesterday. The fact of the matter is that, in some ways, it is a stalling tactic," a few minutes later she remarked, "The party line is that most scientific associations oppose the Dole bill." (S. 657)

It is understandable that a trade association, whose founding member depends for the continuation of its commercial expansion on the purchase of the largest possible numbers of laboratory animals, should fight legislation that calls upon investigators to consider alternatives which could reduce numbers of animals or replace them. It is far less easy to understand why scientific organizations should follow ABR's "party line." It is not to their best interest to do so. They are not making money selling animals. On the contrary, scientists should have an enlightened self-interest in using the smallest numbers of animals possible and treating them as humanely as possible.

I personally regret the necessity to bring to public attention the massive neglect and mistreatment of animals by research facilities in order to demonstrate the urgent need for enactment of H R. 5725. It would be far preferable for the scientific community as a whole to support H R. 5725. The longer scientists allow lobbyists to fight this modest humane bill on their behalf, the more widespread will public knowledge of laboratory animal suffering become.

Some scientists may have been led to believe that NIH will take care of the problem. It is important that the Congress know that NIH alone is incapable of dealing with it. While we welcome any improvement in NIH's Guide on the Care and Use of Animals, and in the principles recently put forth by NIH (we submitted testimony on both), this activity not only lacks the necessary legal force but, more seriously, lacks any practical means of enforcing the recommendations and principles. As NIH itself emphasizes, it does not want to be a policeman. That task has been properly assigned by the

Congress to USDA regulatory veterinarians.

FARM ANIMALS ARE EXEMPT

As an amendment to the Animal Welfare Act, H.R. 5725 is administered by the Secretary of Agriculture. Agricultural interests should be especially pleased by this fact, and indeed the majority are. Regrettably, others, though totally exempt from the bill's requirements, nevertheless oppose its enactment. They do a distinct disservice to the farmers who are their constituency by opposing a much needed humane bill which farmers as individuals would take not interest in opposing.

H.R. 5725, specifically exempts farm animals because it amends the Animal Welfare Act which excludes from the definition of the term "animal" "horses not used for research purposes and other farm animals, such as but not limited to, livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber."

This exemption has been in place for years and though this is the third time amendments to the Act have been proposed (amendments were passed in 1970 and 1976) no change has ever been proposed to the exemption. The Act focuses on biomedical research and testing laboratories, their animal suppliers, and the transportation of these animals and other dogs, cats and wildlife exhibited in zoos and circuses.

ENFORCEMENT OF THE ANIMAL WELFARE ACT

As demonstrated in the findings from USDA inspection reports on the 186 institutions referred to earlier, a great deal of necessary work has been conducted by Veterinary Services in seeking correction of deficiencies and alleged violations of the Animal Welfare Act. The difficulties experienced by inspectors in many instances in obtaining compliance are reflected in these reports.

Large institutions receiving tens of millions of dollars each year from NIH often brush off the veterinary inspectors' efforts to persuade them to correct abuses as required by the Animal Welfare Act. Persistent visits and revisits, and the statement that a legal case will be filed if the institution continues its irresponsible course are frequently necessary.

Basically, the problem stems from poor work by the Office of General Counsel where many a case has waited for months or even years for action. Often the legal work, when finally accomplished, is inferior and fails in its purpose. OGC should provide the deterrent which would ease the inspectors' task throughout the country. We strongly recommend that this

distinguished subcommittee demand that OGC give the Animal Welfare Act high priority and carry through effectively on cases. The current and past failure to do so results in needless waste of government funds when inspectors are forced to make repeated visits to obtain compliance. In the meantime, animals may suffer sicken, and die for lack of compliance with the minimum standards. Veterinary Service's classification of both major and minor deficiencies is attached (Appendix A). Note number 2 in the "major" classification: "Excessive fecal buildup to the point where it appears that weeks or even months have transpired since the last cleaning." It is unpleasant to realize the University of Rochester fell into that category: 7/20/82 "Primates in Room B-7573B are being kept in cages which have not been sanitized for over six (6) weeks. (Since 6/1/82)".

Further excerpts from inspection reports are given in a summary which I would submit for the hearings record.

Based on our observations of USDA enforcement activity from the time of the bill's passage in 1966 till today, the Society for Animal Protective Legislation makes the following recommendations:

1) Although inspection is better today than it has ever been, considerable improvement is still required to bring it up to uniformly high standards. The Subcommittee should ask for regular reports on the measures taken by Veterinary Services to make the program effective.

At a minimum such a program should include a) training sessions, b) methods of rewarding good and discouraging poor enforcement by all personnel, c) Prompt reporting of deficiencies found in all federally funded institutions to the funding body (The Memorandum of Understanding instituted for flow of information among NIH, USDA and FDA seems to lack urgency in execution. Thus NIH peer review panels are generally unaware of the findings of the USDA veterinary inspectors even when animal welfare standards are grossly neglected).

2) The Subcommittee should ask for a full report by the Office of General Counsel on its preparation and handling of cases under the Animal Welfare Act, and direct OGC to seek deterrent action so the law can no longer be disregarded with impunity as has often been the case during the past 18 years.

3) The Subcommittee should make clear to the Secretary of Agriculture that any shifting of funds away from the Animal Welfare Act for other purposes will not be tolerated in the future.

4) The Subcommittee should urge the Secretary to increase the number of Animal Care Specialists so that laboratory

inspections are not neglected when animal disease emergencies take priority among the general inspectors.

References

- (1) American Association of Biological Sciences, testimony before the Subcommittee on Agricultural Appropriations, representing: American Society of Cell Biology, Association of American Medical Colleges, Federation of American Societies for Experimental Biology, National Foundation for Infectious Diseases, National Society for Medical Research, and the Public and Scientific Affairs Board of the American Society for Microbiology.
- (2) Bennett, Susan, and Price, Debbie M., "Animal Rights Unit Claims Penn Raid," Philadelphia Daily News, May 30, 1984.
- (3) National Institutes of Health grant, "Head Injury Clinical Research Center," Number NS 08803-13.
- (4) "Proposed Public Health Service Policy on Humane Care and Use of Animals by Awardee Institutions."
- (5) Boffey, Philip M., "The Mouse Mix-up", New York Times, July 27, 1982.
- (6) "Scientist Sues Over Genetically Impure Mice", by Jeffrey L. Fox, Science. (Vol. 221, August 21, 1983).

(Attachments follow:)

APPENDIX A

Through the Freedom of Information Act U.S. Department of Agriculture veterinary inspectors reports were requested for 186 randomly selected research institutions. Those 186 institutions are listed in Categories I, II, III, IV, or V according to the data found in the inspection reports.

Category I consists of 44 institutions that had major and repeated major or minor deficiencies.

Category II consists of 41 institutions with less numerous but still major and/or repeated major or minor deficiencies.

Category III consists of 3 institutions for which inspection reports were exempt from disclosure under 5 U.S.C. 552 (b)(7)(a) which allows the Agency to withhold investigatory records compiled for law enforcement purposes if their disclosure could interfere with enforcement proceedings.

Category IV consists of 53 institutions with minor deficiencies.

Category V consists of 45 institutions with no deficiencies reported.

U.S. DEPARTMENT OF AGRICULTURE VETERINARY SERVICES NOTICE

A. Minor Deficiencies

These are deficiencies of the standards or regulations which, due to their nature, would not pose a direct or immediate safety or health hazard to the animals involved. They also include those deficiencies which could potentially pose a safety or health hazard but, on the inspection date, are not observed in a severe or acute state. Examples include:

1. Inadequate records or animal identification.
2. Small clumps of weeds which border outdoor primary enclosure in which, however, no signs of pests are present.
3. Fecal buildup of no more than 2 days' duration.
4. Watering receptacles which appear not to have been cleaned and sanitized within the previous 2 weeks.
5. Primary enclosures which contain a few loose wires.

B. Major Deficiencies

These are deficiencies of the standard or regulations which, due to their nature, would usually constitute a health or safety hazard to the animals involved. They also include those deficiencies which, due to continuing neglect or advanced state of deterioration, constitute a safety or health hazard on the inspection date. Examples include:

1. Animals in obvious need of veterinary care.
2. Excessive fecal buildup to the point where it appears that weeks or even months have transpired since the last cleaning
3. Primary enclosures and surrounding areas show evidence of dead rats, rat feces, rat holes, and other indications of major pest infestation.
4. Primary enclosures in an advanced state of structural disrepair, even to the point that it is possible for the caged animals to escape or for outside animals or predators to enter, or where the caged animals can seriously injure themselves
5. Indoor housing facilities with little or no ventilation, possibly to the point that the overpowering odors and ammonia scent are disagreeable to the inspector's well-being.
6. Vermin infested feed.
7. Lack of feed and water.

(REVISED OCTOBER 1984) **CATEGORY I**
Major and repeated major or minor deficiencies

	RESEARCH INSTITUTION	AAALAC ACCREDITED	YEAR	NIH GRANTS \$	TOTAL	# OF ANIMALS						INCREASE IN # OF ANIMALS	PAINFUL EXPERIMENTS WITHOUT PAIN RELIEVING DRUGS - 1983 **
						DOGS	CATS	GUINEA PIGS	HAMSTERS	RABBITS	PRIMATES		
1.	Arizona State Univ.		1982 1983	803,637 742,111	895 1065	148 165	55 13	19 30	427 537	246 320	-	X	0
2.	University of Arizona	X	1982 1983	13,719,002 14,120,949	4923 5571	640 506	322 298	960 774	1406 1247	1469 2618	126	X	0
3.	Syntex (USA) Inc. CA		1982 1983	- -	8176 9790	552 635	545 454	3662 5066	1161 1554	1950 1795	306 286	X	260 dogs, 1260 g. pigs, 871 rabbits, 115 primates
4.	Colorado State Univ.		1982 1983	3,271,966 4,034,313	3113 3089	2108 1732	407 289	228 659	185 20	188 389	-		0
5.	Elars Bio Research Labs, CO		1982 1983	- -	1341 23205	153 570	- 112	176 2618	- 18636	1012 1269	-	X	0
6.	Univ. of Colorado Med. School	X	1982 1983	21,781,483 24,530,507	4662 5178	852 682	265 303	327 454	157 278	2874 3283	227 178	X	21 primates
7.	Yale University, CT	X	1982 1983	31,342,691 57,745,597	9817 8258	732 723	465 300	2929 2953	2134 1046	3379 3202	178		0
8.	Howard Univ., D.C.	X	1982 1983	4,841,231 6,173,549	897 1021	169 119	187 144	81 275	238 377	215 103	7 3	X	0
9.	Univ. of Florida at Gainesville Vet. Med., J. H. Miller Rlth Ctr.	Sch. of Med. Dent., Pharm.	1982 1983	12,115,513 13,432,365	6953 4079	1840 1234	639 409	505 577	1973 363	1895 1397	101 99		0
10.	Univ. of Miami, FL		1982 1983	14,459,339 14,620,941	3198 3098	232 346	256 280	299 285	162 133	1837 1712	412 342		0
11.	Emory University, GA		1982 1983	14,229,952 16,882,407	6216 4001	759 667	218 55	272 363	125 -	2607 631	2235 2285		0
12.	University of Georgia	X	1982 1983	8,306,329 8,574,835	52701 26498	1983 1438	416 359	498 392	44076 19406	5446 4655	284 248		0

(REVISED OCTOBER 1984)

CATEGORY 1 continued

	RESEARCH INSTITUTION	AAALAC ACCREDITED	YEAR	NIN GRANTS \$	TOTAL	# OF ANIMALS					INCREASE IN # OF ANIMALS	PAINFUL EXPERI- MENTS WITHOUT PAIN RELIEVING DRUGS - 1983 **
						DOGS	CATS	GUINEA PIGS	HAMSTERS	RABBITS	PRIMATES	
13.	University of Hawaii	X until 1984	1982 1983	4,575,195 5,370,782	3524 3456	37 21	370 293	258 416	2298 2400	456 275	105 31	0
14.	Hektoen Inst. for Med. Research, IL		1982 1983	99,293 -	432 723	200 210	22 33	30 30	- 25	130 420	30 5	0
15.	University of Chicago, IL		1982 1983	31,399,137 36,816,448	3582 3517	1216 1304	25 60	505 266	137 65	1438 1432	281 390	63 primates
16.	Purdue University., IN	X Pharmacy Sch.	1982 1983	9,094,043* 9,287,881*	2179 1726	786 657	8 18	291 291	300 447	773 313	21 -	13 g. pigs
17.	Louisiana State Univ., LA	X Med. Ctr. & Vet. Med.	1982 1983	9,842,611 10,605,223	5311 5747	1532 1534	311 217	649 782	719 835	1942 2199	158 184	0
18.	Johns Hopkins Univ., MD	X Medical Instn.	1982 1983	51,127,460 60,673,430	11045 10781	3459 2270	160 215	876 1322	1811 1606	4620 5287	119 81	3 rabbits
19.	University of Maryland	Sch. of Med. Dent. beg. '83-'84	1982 1983	15,862,279 13,833,139	1837 4767	86 321	13 62	1007 1434	371 1876	294 1037	68 37	0
20.	Beth Israel Hospital, MA	X	1982 1983	6,467,629 7,174,350	2762 2919	363 346	5 20	1364 1410	110 116	912 1017	8 10	0
21.	Harvard University, MA	Med. Dent. P. Hlth. Schs. An. Res. & Primate Ctrs	1982 1983	55,627,121 56,142,371	9244 9410	2321 1721	575 250	2305 1984	1984 3826	1561 1273	488 356	0
22.	Tufts New England Med. Ctr., MA	X	1981 1982	1,314,767 743,573	1761 2005	211 180	143 27	227 272	188 209	958 1285	34 32	0
23.	University of Mass., at Worcester	X Med. Ctr.	1982 1983	6,556,969 8,951,435	1286 1757	347 597	28 59	322 334	51 -	736 753	2 14	0

(REVISED OCTOBER 1984)

CATEGORY I continued

	RESEARCH INSTITUTION	AAALAC ACCREDITED	YEAR	NIH GRANTS \$	TOTAL	# OF ANIMALS					INCREASE IN # OF ANIMALS	PAINFUL EXPERIMENTS WITHOUT PAIN RELIEVING DRUGS - 1983 **
						DOGS	CATS	GUINEA PIGS	HAMSTERS	RABBITS	PRIMATES	
24.	Warner-Lambert/Park-Davis, MI		1982 1983	- -	8539 16394	1423 1297	9 8	6421 11741	64 -	519 3202	94 146	X 70 g. pigs
25.	Univ. of Minnesota	Duluth Med. Coll.	1982 1983	41,060,675 40,860,135	11188 8563	3251 2715	1026 1054	1923 1421	866 757	4088 2527	34 89	7 dogs
26.	Univ. of Mississippi		1982 1983	4,382,482 4,259,155	2407 2898	887 1050	76 178	199 358	248 332	921 899	76 81	X 0
27.	Washington University, MO		1982 1983	39,111,960 42,895,879	9086 9481	980 1335	397 581	1952 1560	1455 739	4191 5107	111 159	X 0
28.	Rutgers, The State Univ NJ		1982 1983	8,644,703 9,898,731	4701 2593	26 14	26 6	1881 1391	1407 925	1332 236	29 21	0
29.	Cornell University, NY at Ithaca	NY State Coll. of Vet. Med.	1982 1983	10,882,713 13,488,271	3248 1847	1624 326	542 101	272 181	251 419	548 810	11 10	2 g. pigs
30.	New York University, NY		1982 1983	25,401,805 32,559,848	4749 3804	262 310	473 197	967 880	1580 1529	1010 448	457 440	0
31.	State Univ. of NY at Downstate Med. Ctr. a	X	1982 1983	6,014,228 6,675,186	1948 1796	374 374	261 400	352 249	232 72	476 449	253 252	0
31.	State Univ. of NY at Stony Brook b	X	1982 1983	11,759,599 13,303,972	1906 1504	328 226	293 244	211 -	694 621	337 368	43 45	0
	Univ. of Rochester, NY	X	1982 1983	25,991,504 31,195,681	1781 2366	763 836	145 127	124 271	134 441	505 595	130 96	X 3 cats, 1 rabbit, 5 primates
32.	Duke University, NC	X	1982 1983	34,749,791 39,206,042	6168 5347	1784 2033	540 483	1243 466	207 382	2351 1975	23 28	219 g. pigs, 20 rabbits
33.	Univ. of NC, at Chapel Hill	X	1982 1983	26,627,702 27,914,081	5557 5912	1306 1251	594 463	787 775	917 1229	1914 2088	39 106	X 48 dogs, 12 cats, 15 primates

(REVISED OCTOBER 1984)

CATEGORY 1 continued

	RESEARCH INSTITUTION	AAALAC ACCREDITED	YEAR	NIH GRANTS \$	TOTAL	# OF ANIMALS							INCREASE IN # OF ANIMALS	PAINFUL EXPERIMENTS WITHOUT PAIN RELIEVING DRUGS - 1983 **
						DOGS	CATS	CUTNEA	PIGS	BAMSTERS	RABBITS	PRIMATES		
35.	Case Western Reserve Univ., OH		1982 1983	22,809,820 26,504,774	4076 3588	734 892	728 389	434 354		879 683	1255 1241	46 28		8 rabbits
36.	Ohio State University Sch. of Dent. Med., Pharm., Lab. An. Ctr., Dept of An. Labs. Hosp.		1981 1982	10,052,295 10,023,942	7363 5813	1624 1926	581 558	1410 813		1862 861	1762 1579	121 76		0
37.	Oregon Regional Primate Center		1982 1983	3,504,063 3,703,858	3164 2554	- -	- -	85 10		354 171	82 68	2643 2403		0
38.	Univ. of Oregon Med. School		1982 1983	8,118,117 8,385,213	1944 1705	627 530	139 103	663 378		- 50	314 411	1 33		0
39.	Univ. of Pittsburgh, PA Sch. of Med	X	1982 1983	17,552,164 21,329,559	3417 3376	770 703	257 256	590 1156		12 15	1428 930	360 316		0
40.	Univ. of Rhode Island		1982 1983	459,226 685,693	123 119	- -	- -	94 40		- -	20 69	9 9		0
41.	Vanderbilt Univ., TN	X	1982 1983	23,672,337 25,630,540	5482 5299	1375 1498	24 37	553 367		622 989	2611 2205	297 223		0
42.	Univ. of Virginia, Charlottesville	X	1982 1983	14,173,863 15,450,233	5251 4154	568 958	273 230	1269 475		750 818	2342 1617	69 56		0
43.	Med. Coll. of Wisconsin	X	1981 1982	8,418,095 7,262,148	3449 3190	1380 1176	309 251	46 189		212 158	1406 1349	96 67		0
44.	Univ. of Washington	X since 1982	1982 1983	45,184,408 54,501,581	9359 9221	1018 993	401 642	791 429		2807 2872	3263 2413	1075 1872		16 primates

* Involving only animals listed in this chart.

** Underenforcement of this requirement and the resultant underreporting means that many institutions erroneously fail to acknowledge unrelieved pain and those who do acknowledge it in only a small number of animals.

Addendum to Category I

Many of the institutions in Category I received from NIH Research and Development Contracts in addition to the NIH research grants recorded in the chart. The following list shows the contract totals for each institution in 1983.

1. Arizona State Univ.,	\$ -
2. University of Arizona,	1,577,794
3. Syntex (USA) Inc., CA,	604,880
4. Colorado State Univ.,	123,671
5. Elars Bio Research Labs, CO,	-
6. Univ. of Colorado,	244,628
7. Yale University, CT,	1,826,492
8. Howard Univ., D.C.,	715,515
9. Univ. of Florida at Gainesville,	46,530
10. Univ. of Miami, FL,	1,610,992
11. Emory University, GA,	896,274
12. University of Georgia,	340,355
13. University of Hawaii,	679,258
14. Hektoen Inst. for Med. Res., IL,	-
15. University of Chicago, IL,	5,514
16. Purdue University, IN,	-
17. Louisiana State Univ.,	275,742
18. John Hopkins Univ., MD,	4,219,430
19. University of Maryland,	4,841,934
20. Beth Israel Hospital MA,	187,439
21. Harvard University, MA,	2,017,034
22. Tufts New England Med. Ctr., MA,	411,246
23. University of Mass., at Worcester,	40,502
24. Warner-Lambert/Park-Davis, MI,	1,009,430
25. Univ. of Minnesota,	3,962,015
26. Univ. of Mississippi,	94,887
27. Washington University, MO,	1,189,360
28. Rutgers, The State Univ., NJ,	-
29. Cornell University at Ithaca, NY,	517,308
30. New York University, NY,	391,758
31a. State Univ. of NY at Downstate Med. Ctr.,	217,146
31b. State Univ. of NY at Stony Brook,	316,955
32. Univ. of Rochester, NY,	1,151,807
33. Duke University, NC,	1,279,019
34. Univ. of NC at Chapel Hill,	7,002,462
35. Case Western Reserve Univ., OH,	496,841
36. Ohio State University,	564,557
37. Oregon Regional Primate Center	-
38. Univ. of Oregon Med. School,	45,639
39. Univ. of Pittsburgh, PA,	3,730,401
40. Univ. of Rhode Island	-
41. Vanderbilt Univ., TN,	735,810
42. Univ. of Virginia at Charlottesville,	375,708
43. Med. Coll. of Wisconsin,	476,753
44. Univ. of Washington	4,775,379

Category II

Major and/or repeated major or minor deficiencies

1. Jackson Laboratories, Inc., D.C.
2. University of Alabama, Birmingham, AL
3. Standard Brands, Inc., NY
4. University of Utah, UT
5. University Health Center of Pittsburgh, PA
6. University of Kentucky, KY
7. Mayo Foundation, MN
8. University of Missouri, MO
9. University of Iowa, IA
10. University of Wisconsin - Madison, WI
11. Columbia University, NY
12. Stritch School of Medicine/Loyola University IL
13. Foundation for Behavioral Research, MI
14. Hazelton Research Primates, VA
15. Dartmouth College, NH
16. Pharmacopathics Research, MD
17. Abbott Labs IL
18. Utah State University, UT
19. Kansas University Medical Center, KS
20. Brigham Young University, UT
21. ICI Americas Inc DE
22. Norwich-Eaton Pharmaceuticals, NY
23. Bristol Laboratories, NY
24. Schering Corporation, NJ
25. Flow Laboratories, VA
26. Marquette University, WI
27. Mount Sinai Hospital, WI
28. Biomedical Research Labs, WA
29. Hollister - Stier Labs, WA
30. Creighton Univ./School of Medicine, NE
31. Princeton University, NJ
32. University of Nevada, NV
33. The Cleveland Clinic, OH
34. Shriners Burns Institute, MA
35. Bioassay Systems Co., MA
36. Bates College, ME
37. Michael Reese Hospital & Medical Center, IL
38. Kansas State University, KS
39. Yeshiva University, NY
40. University of South Florida, FL
41. Litton Bionetics, MD

Category III

Exempt from disclosure. The Freedom of Information Act allows the agency to withhold investigatory records compiled for law enforcement purposes if their disclosure could interfere with enforcement proceedings.

1. University of Connecticut, CT
2. University of Texas, Austin TX
3. Michigan State University, MI

Category IV

Minor deficiencies

1. American Red Cross, MD
2. Grady Investments, Inc., OH
3. University of Illinois, IL
4. Massachusetts Institute of Technology, MA
5. University of Kansas, Lawrence, KS
6. Indiana University, IN
7. Brandeis University, MA
8. Avon Products, Inc., NY
9. Colgate University, NY
10. Cintichem, Inc., NY
11. University of Nebraska, NE
12. University of New Mexico, NM
13. Children's Hospital of Pittsburgh, PA
14. University of Pennsylvania, PA
15. Sloan-Kettering Institute, NY
16. Southwest Foundation for Research Education, TX
17. Eli Lilly & Co., IN
18. River Valley Farms, MN
19. Immuno Nuclear Corp., MN
20. Tox Monitor IL
21. Medical College of Pennsylvania, PA
22. Southwest Research Institute, TX
23. Temple University, PA
24. Hazelton Labs Inc., VA
25. Tufts University, MA
26. Arthur D. Little, IL
27. Toxicity Research Lab., MI
28. Travenol Labs., IL
29. University of Oregon, OR
30. Quaker Oats Co., IL
31. University of S. Alabama, AL
32. Environmental Consultants, VA
33. University of Tennessee, TN
34. University of Texas, El Paso, TX
35. St. Louis University, MO
36. Merrell Dow Pharmaceuticals, OH
37. EG & G, MA
38. University of Utah Research Institute, UT
39. University of California, Santa Cruz, CA
40. University of Texas, Dallas, TX
41. Chicago Medical School, IL
42. Massachusetts General Hospital, MA
43. Illinois Department of Mental Health, IL
44. Ortho Research Institute, NJ
45. American Cyanamid Co., NJ
46. Allied Chemical Corp., NJ
47. Father Flanagan's Boys Home, NE
48. Merck & Co. Inc., NJ
49. Tulane University, LA
50. University of Idaho, ID
51. Meloy Labs, VA
52. Childrens Hospital of DC, DC
53. University of Michigan, MI

Category V

No deficiencies

1. University of South Carolina, SC
2. Schwartz College of Pharmacy, NY
3. Northwestern University, IL
4. Mt. Sinai Hospital School of Medicine, NY
5. St. Vincent's Hospital, NY
6. University of Cincinnati, OH
7. Gillette Comp. Research Institute, MD
8. Lovelace Foundation of Medicine, NM
9. Eastern Kodak Co., NY
10. Southern Illinois University, IL
11. Thomas Jefferson University, IL
12. Philadelphia College of Osteopathic Medicine, PA
13. Texas Research Institute of Mental Science, TX
14. University of Alabama, University, AL
15. Cook County Graduate School of Medicine, IL
16. University of Oklahoma, OK
17. Latter Day Saints Hospital, UT
18. Cornell University Med. College, NY
19. Gulf South Research Institute, LA
20. The Jackson Laboratory ME
21. Lahey Clinic Foundation, MA
22. Rockefeller University, NY
23. Childrens Hospital of Philadelphia, PA
24. Baylor University College of Medicine, TX
25. Hazleton Raltech Inc., WI
26. Smith Kline Corp., PA
27. Bristol Myers Pharm. Research & Develop. Co., NJ
28. Medtronic Inc., MN
29. G.D. Searle & Co., IL
30. Boehringer Ingelheim Ltd., CT
31. Dow Chemical Co., MI
32. E. Tennessee State University, TN
33. Shriners Hospital for Crippled Children, IL
34. Monsanto Company, MO
35. Mallinckrodt Chemical Works, MO
36. Diamond Shamrock Corp., OH
37. Ohio Valley Medical Center Inc., OH
38. Bodil - Schmidt - Nielson, ME
39. University of Texas, Tyler, TX
40. University of Texas, Galveston, TX
41. Riker Lab, MN
42. Allergan Pharmaceutical, CA
43. Armour Pharmaceutical, IL
44. Brown University, RI
45. Hahnemann Medical College & Hospital, PA



ANIMAL WELFARE INSTITUTE

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A Summary of Deficiencies and Apparent Violations of the Federal Animal Welfare Act in Eleven AAALAC-accredited Institutions

by Christine Stevens and Louise Wright

Under the Freedom of Information Act, inspection reports made by veterinary inspectors of Veterinary Services, Animal and Plant Health Inspection Services, U.S. Department of Agriculture of a number of registered research facilities which have been accredited by the American Association for Accreditation of Laboratory Animal Care were examined. Excerpts from the reports are given.

The Johns Hopkins University School of Medicine including Baltimore City Hospital and Good Samaritan Hospital, and the School of Hygiene and Public Health have been AAALAC-accredited since 1979. The institution received \$51,127,460 from NIH in 1982. Following are a few examples from USDA veterinary inspectors' reports on different areas. 2/22/82 "Dogs and cats must be ID to records at all times by tag on collar or distinctive and legible tattoo marks...This should be corrected immediately." Numerous sanitation deficiencies were also noted. 6/3/82 "Several outdated drugs stored in medicine cabinet...rodent feces and roaches in a cabinet under the sink in the primate building. Also rodent feces were found in the feed room...peeling paint in primate cages...and kennels...all dogs not ID properly should be done immediately" (This seems to be a recurring problem). 10/4/83 "Rabbit rooms A-6 and A-5 have very poor air exchange...stinking with bad odors...In monkey room no. A-19 paint is chipping off at 4 different places in the wall contributing to inadequate sanitation." "In room No. 4-14213 and 4-142A where 3 and 4 monkeys are housed respectively, the primary enclosures were extremely dirty. The urine and feces receptacles were full of urine and excreta, and the monkeys were found wet and smeared with excreta." "In room No. 1357, Dogs N. 2193, 2236, 2243, 2237, 2195, 2194, 2184, 2343 found housed in very small cages...several expired drugs in the medicine cabinet."

3/12/84 "still found an extensive problem with peeling and chipping paint on walls in the dog kennels of the Dog Building and the kennels of the Primate House."

Vanderbilt University in Nashville, Tennessee, has been AAALAC accredited since 1979, yet the October 27, 1981 report shows that primates were held in improperly ventilated areas. The condition continued according to the report 4/27/82, "Not enough air change in room 2147." On 5/20/82, "No water in bottle, leaked out . . . most all of feeders need cleaning." 1/27/84, "Cages need cleaning more often for the squirrel monkeys . . . tree shrews replace cages or repaint. Rusty cages makes cleaning, sanitation, and housekeeping impossible." These tree shrews remained in the dirty, rusty cages for three years, as shown by the notation on the 10/27/81 report, "Remove rust and fecal material from cages in tree shrew room." On that same inspection, it was noted that six research dogs were "not identified." NIH only requires an assurance that an institution is AAALAC accredited in order for it to approve the institution's animal care and welfare. In 1982 Vanderbilt University received \$23,672,537 of taxpayers' money from the National Institutes of Health.

The University of Utah received \$17,360,175 in 1982 and, though AAALAC accredited, had numerous alleged violations under the federal Animal Welfare Act. For example, 6/30/81, "Primates have inadequate space . . . filters are pretty well plugged with hair . . . some of the cages are too small, large rabbits 9-11 lbs. have 432 square inches and they should have at least 540 square inches . . . some of the cages are not high enough that rabbits can stand up . . . feed in some feed containers are contaminated with urine from top cage." An inspection 4/6/82 notes, "Four rabbit cages with young litters. The litter pan takes most of the room, not allowing adequate space for the rabbit." 7/20/82, "Flush cages are marginal in sanitation. Urinary deposits on cages. Three or four heavy (10 lb.) pregnant rabbits too large for cage." 12/9/82, "Doors to outside pens 5, 6, 57, 59, and 60 have been clawed or chewed--holes in surface allow moisture into the wooden doors." The same problem had not been corrected by 3/3/84.

The University of Rochester Schools of Medicine and Dentistry are AAALAC accredited, and the institution received \$25,991,504 from NIH in 1982, yet USDA veterinary inspectors found 7/20/82, "Primates in room 6-7573B are being kept in cages which have not been sanitized for over 6 weeks (since 6/1/82) . . . not being cleaned adequately to prevent contamination of the non-human primates contained therein." It is further noted that the room "has organic matter smeared on walls, and floors are dirty." This violation of the standards is very properly marked as "major." The inspector returned 8/20/82 and found again that "primate cages are not being sanitized at least every two weeks as required . . . dates from 16 racks were taken and of these 12 were overdue . . . an effective program for the control of insects is not being maintained . . . room 6-7573B has organic matter smeared on walls. Floors are dirty. Repeat write-up from 7/20/82."

The University of Pittsburgh Medical School is AAALAC accredited. The university received \$17,552,164 from NIH in 1982, yet veterinary inspections by USDA show:

7/25/83, "There were several holes in the wall of the cat room located at the first floor . . . the floor was dirty . . . cat room 575B used as a storage area, one of the feed bags found open and spilled on the floor. There was insufficient light and the room did not appear to have been cleaned for a long time. We recommend periodic cleaning. The light should be uniformly diffused throughout the animal room and supplies, boxes, and Fiberglas cages should not be stored in the animal room."

9/7/83, "The room did not appear to have been cleaned since the last inspection. The acid, detergents, cages and trash containers must be removed from room 638A. I gave 24 hours for correction. The facility will be inspected for compliance tomorrow, 9/8/83." It was only after the USDA inspector insisted that the deficiency be corrected in 24 hours that this finally occurred.

It is interesting to note that inspectors for AAALAC accreditation only return once every three to five years! It should not be necessary for USDA veterinary inspectors to return so frequently as noted in this case in order to obtain compliance with such obviously necessary standards, but it is equally clear that only such insistence by the government can achieve even minimum standards.

Harvard University received \$46,257,040 from NIH in 1982. Harvard Medical School is AAALAC accredited, yet USDA inspections since 1981 show multiple alleged violations of the Animal Welfare Act beginning 9/21/81, where the inspector urges that "chains with multiple hooks must be eliminated. Small chain and no hook at end allowed." The reference is to primates and squirrels. Too small rabbit cages are also noted. 4/28/82, rabbit cages are still too small, as are those for a number of the primates. The report states, "Restraint chairs very dirty. Should be changed each time animals changed. Primary enclosures shall be sanitized often enough to prevent accumulation of debris and excreta."

4/28/82, rabbit cages continue to be too small and self-feeders were not being cleaned out as needed "to prevent molding, deterioration and caking of feed." Two dogs were confined to cages too small for them.

11/17/82, rabbits continue to be confined to cages so cramped that they violate minimum standards. The quarantine room for 13 squirrel monkeys had inadequate ventilation and "fluctuations in temperature are too drastic. Thirty days to correct." In a list of old, rusty, difficult-to-clean cages, the following animals were housed:

3rd Floor

Room 306A	11 monkeys (Cebus)
306B	12 monkeys (Cebus)
306C	22 gerbils
306G	10 monkeys (Cebus)
306H	25 monkeys (Cebus)
302	8 monkeys (Cebus)
333	8 rhesus
337	20 squirrel monkeys
345	16 monkeys (Cebus)
304	3 squirrel monkeys

4th Floor

Room A	37 guinea pigs
	400 gerbils

Basement

Room B39	6 rhesus	5 baboons
B35	5 dogs	
B37	5 dogs	
B31	11 dogs	
B29	10 dogs	
B33	8 cats	
	2 dogs	
B17	87 guinea pigs	
B15	103 guinea pigs	
B13	22 rabbits	

Building 1, 9th Floor

Room 914A	19 cats
914B	22 cats
914C	14 cats

3/15/83, "Two cages inspected with squirrel monkeys had loose, sharp wires on the caging where openings are located. Other parts of the cages were rusted and deteriorated . . . It appears sanitation is nonexistent while animals are in isolation chambers. Areas around isolation chambers could be improved in housekeeping by sink, floors, etc."

Yale University's School of Medicine was AAALAC-accredited in 1979. The accreditation has never been lifted, nor have any problems occurred with NIH, despite the fact that USDA inspections reveal such violations as (2-8-82) both dogs and cats were illegally purchased from Laka, Inc. of Canada. Further, four of the Medical School's sites were repeatedly found to have inadequate caging for both rabbits and primates. For example, Sterling Hall of Medicine was cited for inadequate primate cages (1-14-81, 5-23-82, and 2-4-83). USDA also noted lack of proper ventilation for cats and "excessive build-up of green material" in rabbit water bottles. Yale received \$51,142,691 from NIH in 1982.

The University of Massachusetts Medical Center at Worcester was AAALAC-accredited 2-13-80 according to NIH Statements of Assurance submitted by Dr. William S. Webster, the Attending Veterinarian of the School of Medicine and a member of the AAALAC Council on Accreditation. AAALAC accreditation apparently continued even though Dr. Webster acknowledged multiple violations reported by USDA inspectors, including inadequate cages for primates and dogs in 1982 and for rabbits in 1981, '82' and '83. In 1981 the USDA inspector noted build-up of feces and other waste in some of the institution's animal rooms, and in both 1981 and '82 ventilation systems were not functioning properly. Heavy odors permeated areas where drains were clogged with feces.

A more unusual violation is Dr. Webster's purchase of dogs from unlicensed sources, e.g. from one Ed Gauvin who provided greyhounds from Connecticut: "Dr. Webster informed us this would cease as of today (6-11-81)...Any money exchanged after this date will result in an alleged violation being filed," according to the USDA report. Nevertheless, on 2-24-82, "A review of the records indicated U Mass did pay the Clinton dog officer money for transporting the dogs to U Mass as well as paying the town for the dogs...U Mass must cease paying transportation charges for dogs, cats or other animals unless they are licensed as dealers with USDA."

On 12-3-82 dogs were found overcrowded and in cages too small for them. The report also notes, "Where two greyhounds are housed together, they are both muzzled, making eating pellets difficult."

On 2-9-83, "Ventilation - Dogs. Many ventilation filters are clogged with shavings, hair, dust." Also, "a number of water bottles have a green film coating the inside."

These are just a few of the many deficiencies noted in the 81-83 reports, including "build up of rabbit feces on floors of cages," "odor of dog urine and feces strong," "large amount of fecal material and wet shavings in run. This pen should be cleaned today." and "6 large rabbits weighing over 12 lbs. (we weighed two with Dr. Webster) Rabbits over 12 lbs. must be provided an area of 720 square inches. Cages are 25" by 24" or 600 square inches." The university received \$6,556,969 from NIH in 1982.

Two AAALAC-accredited institutions in the State University of New York system show abuses so serious and so often repeated that USDA inspectors recommended prosecution. Meantime, these institutions apparently remain in NIH's good graces based on their Statements of Assurance that they are AAALAC-accredited. For example, USDA reported August 19, 1982: "The dogs need rest boards in the runs to stay clear and away from dampness, urine and feces. The dogs were found to be sitting in urine and feces." Two months later the inspector reported: "On the previous inspection dated 8-19-82, it was pointed out that drainage of dog quarters is very

defective and accumulation of urine, feces, waste water and food in the area creates a potential health hazard for the animals. Nothing has been done so far to rectify the deficiency. A case against the facility is recommended.' The Stony Brook campus uses large numbers of dogs. The most recent figures available (10-1-82) show 328.

In the case of Downstate Medical Center, the inspector complained 8-5-81: "There are four cats enclosed in one cage 28" x 32" making it very uncomfortable for them to turn about freely and to stay in their normal position. It is impossible for the group to sit and lie comfortably. This deficiency should immediately be rectified." He added that the cages "were found in very dirty condition." Despite warnings, rabbits were repeatedly found in cages too small for them. A case against the facility was recommended 5-27-80. SUNY at Stony Brook received \$11,757,599 and SUNY at Downstate received \$6,014,228 from NIH in 1982.



ANIMAL WELFARE INSTITUTE

P.O. Box 3650 Washington, D.C. 20007

Examples of Registered Research Facilities Classed as Category I

(major deficiencies and repeated major or minor deficiencies
in minimum standards under the Animal Welfare Act)

Inspection reports made by United States Department of Agriculture, Animal and Plant Health Inspection Service Veterinary inspectors were requested under the Freedom of Information Act for a random sample of 186 registered research institutions. Of those 186 institutions, 44 were found to have major and repeated major or minor deficiencies constituting apparent violations of the Federal Animal Welfare Act. The following 10 summaries are based on excerpts from those inspection reports.

Since 1979 (if not before) Washington University in St. Louis has been admittedly out of compliance with Animal Welfare Act regulations, according to Statements of Assurance submitted to NIH, OPRR, and yet the amount of grant money given to the University as a whole has increased by nearly a million dollars every year. In 1983 alone the University received \$42,895,879 from NIH. According to USDA required annual reports, 1,335 dogs, 581 cats, 1,560 guinea pigs, 739 hamsters, 5,107 rabbits, 59 primates were used in 1983, constituting an overall increase since 1982 in the number of animals covered by the Animal Welfare Act and used at the University.

Some deficiencies noted by USDA inspectors during the last three years involve sanitation and cleanliness. Examples of these deficiencies include: 1/6/82 "excessive accumulation of excreta in litter boxes," 3/10/82, "Food receptacles in primate rooms were empty and dirty." Also on 3/10/82 it was noted that "several water receptacles in the cat colonies rooms were visibly dirty and felt slimy to the touch."

On 4/22/82, "A sick kitten was observed which was not under the care of a veterinarian [a deficiency in itself]. Blood from rectum and paresis of rear limb. No pain or distress report on file as prescribed by Section 2.28(4) of this regulation."

Beyond the deficiencies mentioned above, ones involving proper identification and record keeping were cited by USDA inspector Arnaldo Vaquer, DVM, on 4/22/82 and 9/27/83. "In one cat room they had 50% of cats without collar and/or ID tag. This deficiency was noted before on last inspection report of 3/16/82." And, "Dogs on hand were 47 at the facility and in the computer printout from OLAC they were supposed to have 134."

The University's Animal Care Committee has regularly made its own inspections of their facilities made recommendations for improvements, and reported progress made each year, all reflected in the NIH Statements of Assurance. Deficiencies noted by the committee have been primarily with cage size, however in late 1983 and early 1984 the committee inspected and noted that "unreported health problems were cited in three of the 21 facilities."

The University of Georgia supports many different sites including the Medical College of Georgia and as an organizational whole received \$8,574,835 from NIH in 1983. The total number of covered animals used by the University in 1983 was 1,438 dogs, 359 cats, 91 guinea pigs, 19,406 hamsters, 4,655 rabbits and 248 primates. USDA inspections covering that year and two previous ones have revealed both major and repeated deficiencies.

On 6/30/83 it was discovered by a USDA inspector that the University had been buying dogs from an unlicensed dealer. "VS Form 18-6 attached for Llaird Kennel 1490 Whit Davis Road Athens, Georgia 30605 (404) 548-1988. With dates of :

5-10-83	4 dogs
5-23-83	4 dogs
5-24-83	3 dogs
6-1-83	2 dogs
6-28-83	1 dog

I have no records that this kennel has a USDA dealer license. "In fact Llaird's Kennel did not appear in USDA's published list of licensed dealers until 1984.

The University has also had repeated problems with proper identification of and records for dogs. On 2/1/82 "Dogs in 1106 D no ID. Dog in 192 also. Some raised dogs in outside runs no ID." and again at the same inspection that dogs were purchased illegally, the USDA inspector reported "1 poodle does not have ID tags."

Another deficiency observed by USDA inspectors was inadequate sanitation that affected both primates, rabbits and guinea pigs. Regarding primates, on 4/29/81 "fecal material build-

up on floor" and on 2/1/82 it was reported that "owl monkeys cages need to be cleaned more often." Those sanitary deficiencies affecting guinea pigs and/or rabbits were cited on 5/13/82, 7/21/82, 8/25/83 and continued to be a problem even in 1984. On 8/25/83 the specific problem was stated as follows: "floor of guinea pig cages are scheduled to be cleaned every Wednesday. Not cleaned this week."

In 1983, the University of Mississippi received \$4,259,155 in grants from NIH, and according to their USDA required annual reports, used 50 dogs, 178 cats, 358 guinea pigs, 899 rabbits and 71 primates. Inspectors made by USDA over the last three years have revealed numerous and repeated problems varying from inadequate veterinary care to inadequate cleaning practices.

On 9/22/81 the USDA inspector reported "1 dog in (L007-3 room) needs resuturing." Apparently the attending veterinarian had not been regularly checking on the animals.

There was also a repeated problem with housekeeping. It was noted on 10/27/83 "Housekeeping needs to be improved to reduce the clutter/excess cages, equipment, used syringes & needles, etc." and again on 1/13/84 "used boxes - syringes - trash on floor in this room."

Deficiencies in cleaning were found on 2/12/81, 12/4/81 7/15/82 and 12/2/82 and a repeated problem with odor was also cited which involved primarily dogs but also some rabbits and monkeys. This deficiency in odor was, as the inspector noted on 2/2/82, "likely caused by improper cleaning or frequency of cleaning" or as noted on 7/8/83 by "overcrowding". It was at inspections made on 8/30/82, 12/2/82, 10/27/83 and 1/13/84 that the problems with odor were noted.

On 10/27/83 the University's metabolism cages for dogs were reported by a USDA inspector, to be inadequate for use; however, on 1/13/84 the same USDA inspector found "metabolic cages currently being used [which] cannot be cleaned & sanitized adequately & are unsatisfactory & cannot be used after March 11, 1984."

According to Statements of Assurance submitted to NIH, OPRR, the University's Animal Care Committee has been actively inspecting their facilities; however, the more serious problems found by USDA inspectors were not addressed.

The University of Colorado was granted \$24,288,934 by NIH in 1983, a substantial increase over their 1982 grant of

\$21,633,327. Likewise the number of animals used by the University in 1983 was larger than their 1982 total. According to their annual reports, 682 dogs, 177 cats, 442 guinea pigs, 270 hamsters, 3,249 rabbits and 178 primates were used during FY 1983.

On 10/7/81 a USDA inspector of their facilities commented on the following problem that affected the entire Boulder campus: "no single person responsible...difficult to find the animals or even know if new species have been added to some unspecified laboratory or newly proclaimed animal room". This problem was readdressed on 2/10/82 when it was also mentioned that the University did not have an Animal Care Committee.

A deficiency directly associated with the animals housed was inadequate veterinary care. 6/24/82 "There are several dogs with distemper. These animals should be isolated or euthanized." As a result of this deficiency and another involving the records on those dogs, the inspector stated that "If the dog conditioning facility is not closed by Sept. 1, 1982 the above deficiencies have to be considered as a violation of the Act and a case may be filed. Deficiencies in record keeping and proper identification were repeatedly noted (on 6/24/82 6/28/82 and 2/14/83). On 6/24/81, specifically it was found that "there is a great discrepancy between the number of dogs actually on hand and the number stated on the records."

During the last 3 years USDA inspectors have also found repeated problems with dog cages that did not meet even the minimum size requirement set by USDA. On 6/28/82 "It appears that the temporary cages used to house the dogs in the north wing are too small for the animals housed in them" and on 2/16/83 "Several dogs are being held in cages which might be adequate for one animal but two animals are held in these cages."

Also at the University of Colorado, an extreme problem with odor and sanitation was cited for primates. On 6/28/82 the deficiency was written up as follows "The rooms used to house the primate colonies are not being cleaned often enough to prevent odors and manure from building up to unacceptable levels. There was a lot of manure on the floors and more than could be expected smeared on the walls and windows of the primate rooms some of the windows were smeared to the point it was difficult to see through them)." This deficiency was not resolved until after the follow-up inspection at which time it was recommended "that a case be filed as a violation of the Animal Welfare Act."

In 1983 Case Western Reserve University in Ohio received \$26,504,774 from NIH and according to their annual reports, used 892 dogs, 389 guinea pigs, 354 cats, 683 hamsters, 1,240 rabbits, and 29 primates.

Two deficiencies found by USDA inspectors reflected an immediate health hazard to the animals involved. On 4/14/83: "Baby guinea pigs (newborn) are being kept on a cage floor of 1/2" wire mesh. This mesh is too large for baby guinea pigs and can result in broken limbs", and "Rabbit #42, sudi ovsky, NZK' in room EB12D has sore hocks. A solid resting surface should be provided for the floor of this rabbit's cage & all rabbit cages."

In 1982 and 1983 the University reported using 44 rabbits in painful experiments without the use of anesthesia, analgesic and tranquilizers. Although an explanation was given for those 44 rabbits the University failed to mention pain described on 7/29/82 by a USDA inspector: "Some of Dr. Pomeranz's guinea pigs that have repeatedly been bled from the eye have ruptured globes or apparent keratitis sicca & ulcerated corneas. These are painful conditions and require veterinary care."

In addition to the above mentioned deficiencies and many other minor ones, on 7/14/83 the USDA inspector noted "There is an accumulation of organic material on the walls of the dogs cages, on ledges, and in corners that has apparently been present more than 2 weeks."

Cornell University in Ithaca, New York received \$10,882,713 in grants from NIH in 1982; the same year that USDA inspectors found so many and major problems with their facilities. In 1982, Cornell reportedly used 1,624 dogs, 542 cats, 272 guinea pigs, 41 hamsters, 810 rabbits and 11 primates. One USDA inspector found that records were not being kept properly even while these large numbers of animals were being used: 3/17/82 "All records must include the name and address of seller or donor and the method of transportation. Several shipments listed do not have this information."

There have been an unwarranted repetition of deficiencies associated with the dogs housed at Cornell. According to USDA Inspection Reports, dogs were found in cages too small for them. On 9/3/81, 10/16/81, 3/17/82, 4/5/82, and 5/8/84, and dog cages were cited as inadequately cleaned and sanitized on 1/25/80 and 7/23/81. One comment that reflects the affect of such conditions on animals was made by the USDA inspector on 3/17/82: "Although dogs have been removed from the poorest caging, there are still dogs digging at the ceiling, making holes in the wall board."

Deficiencies involving rabbits were no less major than those just mentioned: On 1/7/81 and 5/8/84 rabbits were found in crowded in small cages; and on 11/20/80 3/16/82, 12/2/82 and in May 1984 at 3 different locations, cleaning & sanitation of those cages was inadequate. The problem with cleaning & sanitation was recorded on 12/2/82 as follows: "There is no evidence that cages are being sanitized. Pans under rabbit cages have larger quantities of fecal matter in them and no evidence that they are being emptied once/week."

On 1/20/80 "The rabbits in all three rooms of this facility had either no water or very small amounts of water (ie. less than approximately 1-2 teaspoons)."

Cornell has also not been without deficiencies in veterinary care: 7/23/81 "In the cat room, is the breeding colony an emaciated cat with diarrhea, eye discharge was observed. The caretakers did not know if vet care had been provided and stated that he did not think the cat was being treated, had been treated, or had been given an examination. The cat should be removed immediately, given veterinary care, and kept isolated from cats of the breeding colony."

In 1983 Purdue University in Indiana used 657 dogs, 18 cats, 291 guinea pigs, 447 hamsters and 313 rabbits and was granted \$9,287,881 from NIH. Pain without the use of anesthetic, analgesic or tranquilizer was reported in only 13 guinea pigs. Inspections made in 1981 by USDA Veterinarians revealed a University-wide problem with cleaning, sanitation and odor: for hamsters, "Odor problem in this room... ventilation or air exchange seemed to be a problem in B7"; for rabbits, "Urine buildup on cages - some cages becoming rusty... floors dirty, urine on floor... ventilation is still poor"; and for dogs, "Accumulation of feces in dog pens - odor problem".

There also has been a continuing problem with ventilation and temperature control in the dog facilities of the School of Medicine as cited at inspections on 9/23/82, 4/28/83 5/31/83, 8/19/83 and 9/20/83. This deficiency continued to exist even after 6/8/83 when the Dean of Veterinary Medicine requested "his share" of the University's funds. One other deficiency that directly affected the dogs was noted on 9/23/82: "moldy feed in few feeders Rm B113 Lynn Hall."

Tech America Research Center in Colorado previously known as Elars Bio Research Labs, Inc. used 570 dogs, 112 cats, 2,618 guinea pigs, 18,636 hamsters and 1,269 rabbits in 1983 (the same year that a USDA inspector found records on the dogs to be incomplete and not up to standards). At an inspection

made by USDA on 6/8/83 numerous and quite serious problems were found in the facilities for dogs: dog pens and runs were not sanitized properly, "Water pans were empty Water licks were installed but not working", and 2 dogs crowded in one cage. "Cage measure 35" 35" = 1225 sq. in. Dog measures 27" 27" + 6" = 33" 1089 sq. in. Two dogs would require 2178 sq. inches. These cages will accommodate dogs measuring 29" + 6" and only one per cage." The deficiency in cage size was a repeated apparent violation since on 10/15/81 it was reported that "Dog cage measure 8.5 sq. ft... Space needed 15 sq. feet. Approx. 6 dogs appear to be too large for cages."

Colorado State University received a relatively small amount of money from NIH in 1983 but still used 1732 dogs, 289 cats, 659 guinea pigs, 20 hamsters and 389 rabbits. Although many deficiencies cited during the last 3 years by USDA inspectors were corrected before the follow-up inspections there were many reoccurring problems, for instance, rabbits and sometimes guinea pigs were found without water on 5/14/81, 9/10/81, 5/6/82, 3/22/84.

On 9/10/81 rabbits had only "moldy feed" available.

Rabbits were also found in cages that were dirty and too small for them on 5/14/81, 1/21/82, 5/6/82, 3/22/84 and 5/14/81, 9/29/82, 3/22/84 respectively. On 5/14/81 the deficiency in cleaning and sanitation was reported as follows: "Cage must be cleaned often enough to prevent litter buildup from trays above floor mesh".

Also at Colorado State University there was a continuing problem with rodents near the dog facilities as noted on 9/10/81 "Dogs. Evidence of mice still present in service areas", and on 9/29/82 "Dead mouse and mouse feces not removed from inside area between runs."

The University of Chicago used overall fewer animals in 1983 than in 1982 however the number of dogs increased from 1,216 to 1,304 and primates from 261 in 1982 to 390 in 1983. NIH also increased their research grants from \$31,399,139 in 1982 to \$36,816,448 in 1983 even while USDA veterinary inspectors were continually finding deficiencies in their animal care.

On 12/12/83 the USDA veterinarian inspected a site that apparently had not been inspected before. In the reports he commented on the following not uncommon problem: "Note: Many of these sites were not known to Dr. Cera & Dr. Sept until recently when they requested all the Department heads to provide them a list. This is especially true for Dr. McCrea's room J229. Having found him he is being brought

into compliance with University requirements." The major deficiencies in room J229 were written up on 12/9/83 as follows: "Temporary holding rooms and surgery for squirrel monkeys 2 offices unmodified are being used...standard office with wood topped table - for surgery table....Room 229 is used as a surgical site for implantation of electrodes into subject animals [primates] brains. The animals are recovered and then utilized in computerized experiments. They are maintained for a long time post-operatively (Dr. McCrea is a Ph.D. researcher). Such surgery should be done in a sterile manner NOT in a regular office right off a busy hallway with only chemical sterilization of equipment."

The University of Chicago also had a continuous problem with cleaning and sanitation. On 12/20/82 primate cages were found with a "heavy build up of feces and urine" and on 12/7/83 the same problem was noted as cleaning and removal of fecal material needed more frequently. Even with good ventilation the odor was very strong." Rabbit enclosures were repeatedly found in that same condition (12/20/82 and 8/9/83).

On 12/20/82 and 8/9/83 respectively it was reported that "Primate feed being packed into trays by being walked on. This allows contamination" and "Feed in Rm JS-60 is growing things - it's wet & moldy". These deficiencies constitute a major health hazard to the animals involved.

Also at the 12/20/82 USDA inspection it was found that "Dogs in cages during spraying - Receiving backwash from spray. Must be removed from cage and surrounding cages during spray."

(Additional material is held in the committee files.)

STATEMENT
OF THE
AMERICAN HEART ASSOCIATION

The American Heart Association, on behalf of its 120,000 members and over two million volunteers nationwide, appreciates the opportunity to submit testimony to the Subcommittee and express its views on the use of animals in biomedical research and laboratory testing and in particular on H.R. 5725, "Improved Standards for Laboratory Animals Act." Biomedical research is a key element in the overall mission of the Association to "reduce premature death and disability due to cardiovascular disease." Since its establishment as a voluntary health organization in 1948 a substantial portion of the dollars publicly contributed to support the Association have been invested in cardiovascular research.

The establishment of the American Heart Association coincided with the establishment by Congress of the National Heart Institute, now the National Heart, Lung, and Blood Institute. During the ensuing 37 years there has been close interaction between the Association and the Institute in a dedicated effort to direct funds into productive research which will diminish the extraordinary impact which cardiovascular disease has had and continues to have on the health of our Nation.

There can be no question that the result of this research has had a substantial impact on the reduction of cardiovascular disease in the United States. Although cardiovascular disease continues to be the nation's number one killer, the death rates due to cardiovascular disease have decreased by an incredible 33 percent since 1968. The death rates from stroke have decreased by 46 percent over the same period.

These declines have been estimated to have resulted in the saving of and prolonging of the lives of over a million Americans. However, as noted above, the death and disability toll due to these diseases continues to remain excessively high.

Many of the discoveries and breakthroughs which converged to allow these dramatic declines in morbidity and mortality can be traced to the successful conduct of research involving studies with animals. One example, now well known by the public as a major lifesaving technique, is cardiopulmonary resuscitation (CPR). This technique could never have been successfully applied to humans had there not been an interval where the foundation of the technique was developed in experimental animals. Other techniques such as coronary by-pass, cardiac valve replacement, balloon angioplasty and many others are now being used to save victims of cardiovascular disease. None of these techniques and subsequent improvements to these techniques could ever have been developed without initial studies involving animals.

During its entire history of support for biomedical research the American Heart Association has subscribed to the highest standards of humane treatment of animals. We have followed faithfully the evolution of standards prescribed for animal care by the Federal government and we have insisted continuously that these standards be a part of the research protocols supported by the Association. Our experience has been that in the medical centers where the scientists we support carry

out their work, these standards are locally monitored and faithfully followed and enforced.

To the extent that these widely accepted principles are not adequately monitored and require further enforcement the American Heart Association would be sympathetic to additional steps which might be needed to insure that laboratory animals receive humane and compassionate treatment.

The multitude of issues surrounding the use of animals in research, many of which have reached a very high emotional level, are of great concern to the American Heart Association. Because of this, the American Heart Association has established a "Task Force on Research Animal Use" in the hopes of analyzing the issue thoroughly and developing a national policy which is both rational and balanced and beneficial to all concerned. This Task Force, which is comprised of members from numerous disciplines including biomedical research, veterinary medicine, ethics, and the law, will be making its report and issuing its recommendations at the American Heart Association's Annual Meeting to be held this November in Miami, Florida.

Because of the importance of this report and the impact that it will have on the directions and positions that the AHA will take in the coming months and years, we wish only at this time to make some

preliminary comments on H.R. 5725, the "Improved Standards for Laboratory Animals Act."

We commend the Chairman of the Subcommittee, Congressman Brown, for his efforts to introduce legislation which he feels represents a reasonable approach to what has become an emotional issue.

It is clear that the Congressman has given this issue considerable thought. The basic premises and objectives of the legislation are sound.

However, the American Heart Association believes that enactment of H.R. 5725 may not be necessary at this time or at least premature, since most of what the legislation seeks to accomplish can be carried out under existing laws and authorities, and/or is being assessed by on-going or proposed studies. Below are six such areas of activity which address some of the concerns raised by H.R. 5725 and which the American Heart Association supports:

- o We support the NIH's decision to upgrade its guidelines for the use and care of animals in research. We testified early this year in support of the proposed revisions to the guidelines, "NIH Guide for the Care and Use of Laboratory Animals." We understand that these will be issued in final form next year.

- o We support the formation of an Interagency Research Animal Committee to be composed of Federal agencies who have research programs involving animals.

- o We note that the Food and Drug Administration has just issued a report by its Agency Steering Committee on Animal Welfare issues (Federal Register, Vol. 49, No. 186 p. 37473). That Committee was charged with addressing such issues as:
 - a) Are FDA procedures so ordered as to obtain maximum amount of useful scientific information while utilizing the fewest number of animals?
 - b) Is FDA making maximum use of and encouraging the combined development of reliable in vitro alternatives to in vivo methodologies?
 - c) Are mechanisms in place to ensure continuing compliance with the Animal Welfare Act and with the highest standards of animal care?
 - d) Is the historical usefulness of animal testing in human health protection the primary mission of the FDA properly appreciated by our constituents?

- o We support provisions contained in House and Senate reauthorizing legislation for the National Institutes of Health which call for an eighteen-month study by the National Academy of Sciences to assess the current status of the use of live animals in biomedical and behavioral research.

- o We support the request made by Senator Orrin Hatch last year

that the Office of Technology Assessment (OTA) undertake a study which would make a scientific evaluation of alternative methods of animals in research, experimentation, and testing. This study we understand will be issued early next year.

- o We support increased funding for the NIH Division of Research Resources' Animal Resources Program which is responsible for supporting research projects that enable scientists to obtain and use animals effectively in health-related research.

In view of these current activities being carried out by various Federal agencies, the American Heart Association believes that enactment of legislation, at this time, that contains further directives in the area of the use of animals in research may be premature and possibly a duplication of current effort. We would urge that Congress delay action on this issue until the results of current reviews and reports are available.

Once the revisions to the NIH Guide for the Care and Use of Laboratory Animals and the proposed National Academy of Sciences study are complete, all parties concerned with this issue will have a more complete base from which recommendations for action may be formulated. We would be happy to provide this Subcommittee with a copy of the American Heart Association's Task Force on Research Animal Use final report in November as well.

We thank the Subcommittee once again for this opportunity to comment and we look forward to working with you on this issue in the 99th Congress.

Antonio M. Gotto, Jr., M.D., D. Phil.
President

Statement
of the
American Institute of Biological Sciences

Presented to
The Subcommittee on
Department Operations, Research and Foreign Agriculture
of the
Committee on Agriculture
of the
U.S. House of Representatives

on
H.R. 5725
"Improved Standards for Laboratory Animals Act"

September 19, 1984

The American Institute of Biological Sciences (AIBS) is a national confederation of over forty professional societies and research organizations in the life sciences. Together our groups represent some 70,000 working biologists in the biological, agricultural, environmental and medical sciences.

Biologists have watched with considerable interest the progress of proposed legislation aimed at protecting laboratory animals from misuse and poor care. The foundation of that interest is the belief in the absolute requirement that scientists deal with experimental and demonstration animals in a humane manner based upon sound ethics. The AIBS's major points of emphasis focus on ethics of handling research animals, quality of research data, and an overall respect for life.

We are fearful that anti-science sentiments might prevail to the detriment of biological, medical, and veterinary research and training. We are concerned that some critics of live animal studies are unrealistically optimistic in their expectations concerning the usefulness of computer modeling, cell cultures, and other substitutes for live animals. As scientists, we are disturbed by an attitude which would discourage "research duplication" since replicability by other investigators is our only means of verification.

As citizens and as individuals many biologists have been shocked and disappointed by the actions of a small minority of researchers who seem to lack compassion and respect for life. The well-publicized actions of these few and the resulting public reaction have had the positive effect of stimulating increased awareness of animal welfare issues among biologists, institutions, and funding agencies.

The AIBS would encourage congressional initiatives to develop information concerning the extent of live animal procurement, handling, and use in the United States as well as funding support aimed at developing alternatives to the use of live animals. Despite the statement of congressional findings in Section 2 of the "Improved Standards for Laboratory Animals Act", much work must still be done to perfect alternative methods of research, and we would caution against excessive redirection of current research funding. Any such legislation should place the burden of responsibility with the institution and not on a new army of federal inspectors. We further recommend that the monitorship of such a program take into account the differences between legitimate research organizations and process- or production-oriented laboratories.

Many laboratories that use live animals have long-established guidelines for animal care and many have established animal care committees. While some biologists oppose the inclusion of "public representatives" on animal care committees in the belief that this will only lead to confrontation and delay, others believe that generally this requirement will benefit researchers because it offers them an opportunity to communicate to the general public the benefits resulting from live animal research and the high quality of care by most laboratories. Of prime importance, however, is assuring that the outside member is a true representative of the public (the community) and not of one or another special interest group.

At the Institute, we feel the essential features of any legislation must provide for an opportunity for the general public to be informed regarding the extent to which our knowledge of all biology, including human biology, is dependent upon animal

experimentation. We also feel that the federal inspection should focus on the maintenance of quality records within Institutions. . records that will demonstrate an effective animal care program with appropriate on-going supervision. AIBS is continuing its efforts to encourage institutional commitment by research organizations to embrace both the philosophy and practice of proper animal care.

Several years ago, AIBS adopted a statement regarding the use of animals in experimentation. For the record it is included here in its entirety.

Live animals have long been an important tool in the conduct of scientific research and education. In biomedical, agricultural, toxicological, behavioral, and other biological studies, intact animals perform a vital and irreplaceable function, often serving as models for man. No alternative procedures are known that permit the conduct of some critical kinds of research without live animals. The American Institute of Biological Sciences recognizes that live animals will continue to be an important research resource. The AIBS also recognizes that live animals make a meaningful contribution to the educational process. Study of animals in the laboratory enhances student sensitivity to, and understanding of, all living creatures.

The use of animals mandates responsibility to provide quality care and humane treatment. The AIBS endorses the 'Principles of Animal Use' promulgated by the National Institutes of Health and the National Association of Biology Teachers' 'Guidelines for the Use of Live Animals at the Pre-university Level.' Organisms of the lowest phylum consistent with the knowledge to be gained should be used in research and study. Intrusive studies should be discouraged, especially below the intermediate college level. Educators should rely on demonstration and observation. Other procedures deemed necessary should be used under the direct supervision of a qualified instructor. In all circumstances, scientists and educators must fulfill their moral responsibilities to give proper care and human treatment to the animals they use."

We do not feel that H.R. 5725, "Improved Standards for Laboratory Animals Act," would impose major hardships on most laboratories nor would it impede good research. It continues the logical approach of the Animal Welfare Act, which already has established standards, to ensuring good quality humane care and treatment of laboratory animals. If new legislation is considered necessary, we feel it is a much better vehicle for protecting animals and allowing good research than any other provisions under consideration. We suggest the following clarifications and adjustments to certain sections of the bill.

10/11/11 10:00

First, much biological research involves the observation of animals in their field habitats or other natural settings and analysis of their conduct, migration, etc., not only as indicators of innate species behavior and diversity, but also as measures of responses to environmental effects. Therefore, Section 4.(c) should include the following subsections: "(3) Paragraph (1) shall not prohibit the observation, identification, sampling, surveying, retention, or cataloging of animals in their natural habitats, at biological field stations or at zoological parks for purposes of conducting research on their innate biological behavior or their responses to prevailing environmental conditions."

Next, Section 4.(d) establishes the local oversight body as an animal research committee (emphasis added). The clear intent of the amendment is to restrict both the Committee and the Secretary to matters of animal care and not research. Thus, these bodies should be referred to as "animal care committees."

Further, the same section requires that at least one member of the committee be a doctor of veterinary medicine. Given the diversity of research settings that occur throughout the postsecondary level, this is particularly difficult to either justify or meet in every case. The member should "be a person appropriately qualified in the care and handling of animals used by the research facility."

Finally, Section 4.(f) allows suspension or revocation of federal support after notification only. Elementary due process would suggest an opportunity for the research facility to respond to the determinations of noncompliance and take corrective action prior to being penalized. The additional amendment (f) should include the following statement:

"(f) In any case in which the funding Federal agency determines that conditions of animal care, treatment, or practice in a particular project have not been in compliance with applicable standards, despite notification to the research facility, and after it has had adequate opportunity to respond or take corrective measures, that agency shall..."

Next, the inspection services provided by the Veterinary Service Division of USDA's Animal and Plant Health Inspection Service (APHIS) are the proper vehicles for ensuring enforcement of the provisions of the Animal Welfare Act. The problem is that of the 485 animal inspectors in the field, only six are full-time. The remainder are able to devote only about six percent of their time to animal welfare concerns. To be effective, the animal welfare program must have a continuing level of stable appropriations. Adequate funding on a stable and continuing basis would permit APHIS to provide leadership through a professional, well-trained cadre of federal officials who could provide a uniform level of inspection, guidance and correction before regulatory action is required. APHIS could not only strengthen the training of its own staff and allocate more time, effort and personnel to a regular inspection cycle, it could provide services to research centers and local humane groups through such routes as workshops on research standards, federal regulation and modern animal care practices. Increased and improved funding patterns would also enable APHIS to collect and publish better data about the status of animal welfare in research and among licensed dealerships and would also permit better coordination between APHIS and accreditation groups, such as the American Association for the Accreditation of Laboratory Animal Care (AAALAC).

The Federal government supports about fifty-two percent of the biomedical research in this country, with more than a third coming through NIH alone. Thus, there is substantial federal concern that the research standards it establishes in the areas of animal care are met. In this regard, it would be prudent to wait until NIH and other federal entities which are currently revising animal welfare guidelines complete the process to determine the extent to which new legislation is needed and the extent to which it is compatible with new guidelines.

In summary, the American Institute of Biological Sciences considers good care and humane treatment of animals essential to good research, and good research is essential if we are to increase knowledge, conquer disease and illness, and provide plentiful, nutritious food supplies for the world. We feel that better enforcement of the current Animal Welfare Act is in the best interests of the Federal government, the bioscience research community and the humane societies, and that APHIS is the proper agency to administer this Act. If additional legislation is considered necessary, however, then we support the bill, H.R. 5725, with our recommended clarifications to properly protect the integrity of scientific research and its uses in protecting and maintaining human health and welfare.



Washington, D.C. 20540

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AUTHORITY OF THE DEPARTMENT OF AGRICULTURE TO IMPLEMENT PROVISIONS OF
H.R. 5725, 98th CONGRESS, CONCERNING TREATMENT OF LABORATORY ANIMALS

+
Addendum

Henry Cohen
Legislative Attorney
American Law Division
October 24, 1984

AUTHORITY OF THE DEPARTMENT OF AGRICULTURE TO IMPLEMENT PROVISIONS OF
H.R. 5725, 98th CONGRESS, CONCERNING TREATMENT OF LABORATORY ANIMALS

This report considers whether the United States Department of Agriculture (U.S.D.A.) would have the authority, without additional legislation, to implement the provisions of H.R. 5725, 98th Congress, even though that bill was not enacted by the 98th Congress. H.R. 5725, which was entitled the "Improved Standards for Laboratory Animals Act," would have amended the Animal Welfare Act, 7 U.S.C. §§2131-2156, which is enforced by the Secretary of Agriculture. The major changes it would have made to the Act would have been to:

- (1) include federal departments, agencies, and instrumentalities that use animals for research or experimentation within the Act's definition of "research facility" (7 U.S.C. §2132(e)).^{1/}
- (2) require the Secretary to promulgate standards requiring exercise for dogs,
- (3) permit exceptions to the Secretary's standards (on any matter under the Act) to be made only when specified by research protocol,
- (4) require research facilities to provide details to the Secretary of any procedure likely to produce pain or distress in an animal and to consider alternatives to any such procedure,
- (5) require research facilities, in any procedure involving pain to unanesthetized animals, to consult a veterinarian in planning the procedure and to withhold anaesthesia only for the necessary period of time,

^{1/} Under 7 U.S.C. §2144, federal departments, agencies, and instrumentalities must already comply with standards promulgated by the Secretary. Adding them to the definition of "research facility" apparently would make them subject to requirements of the Act apart from the Secretary's standards.

- (6) except as allowed by an animal research committee (see 8 and 9), prohibit the use of any animal in more than one major operation from which it is allowed to recover,
- (7) allow states or their political subdivisions to promulgate standards in addition to those of the U.S.D.A.
- (8) require the Secretary to require each research facility to establish an animal research committee with at least three members at least one of which shall be a veterinarian and another a person having no association with the facility and representing the welfare of animals,
- (9) give animal research committees various duties, including inspecting the research facilities and filing reports of violations of standards with the research facility, with such reports available to the Department of Agriculture,
- (10) require the Secretary to establish an information service at the National Agricultural Library, which shall, in cooperation with the National Library of Medicine, provide information on improved methods of animal experimentation,
- (11) require federal agencies that fund animal experimentation to suspend or revoke federal support if it determines that a research facility has not complied with applicable standards,
- (12) prohibit the Secretary from requiring research facilities to disclose trade secrets or commercial or financial information which is privileged or confidential,
- (13) make it a crime for a member of an animal research committee to release any confidential information of the research facility, and
- (14) authorize civil suits to recover damages sustained as a result of the release of confidential information of a research facility.

Authority of U.S.D.A.

Section 13(a) of the Animal Welfare Act, 7 U.S.C. §2143(a), authorizes the Secretary to "promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors." Section 21 of the Act, 7 U.S.C. §2151, authorizes the Secretary "to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of this Act." The Supreme Court has written:

Where the empowering provision of a statute states simply that the agency may "make . . . such rules and regulations as may be necessary to carry out the provisions of this Act" we have held that the validity of the regulation promulgated thereunder will be sustained as long as it is "reasonably related to the purposes of the enabling legislation."

Mourning v. Family Publications Service, Inc., 411 U.S. 356, 369 (1973). In short, the power of the U.S.D.A. to promulgate regulations under the Animal Welfare Act is very broad. Unless a regulation it promulgates contravenes a law, it is within the agency's authority if it may reasonably be deemed necessary to effectuate the purposes of the Animal Welfare Act. The purpose of the Act essentially is to insure that animals covered by it "are provided humane care and treatment." 7 U.S.C. §2131. Any regulation that is reasonably related to this purpose apparently would be found valid, if challenged in court.

Applying this principle, we have examined the 14 provisions of H.R. 5725 listed above and reached the following conclusions.

Numbers (2) through (6), (8) through (10), and (12) apparently could be implemented by the U.S.D.A. under its existing authority. Specifically, promulgating standards requiring exercise for dogs, requiring research facilities to

consider alternatives to painful experiments, requiring research facilities to establish animal research committees, and implementing the other provisions included in these numbers would appear reasonably related to insuring the humane care and treatment of animals covered by the Act. A qualification to this statement should be made, however. Although U.S.D.A. apparently could establish an information service at the National Agricultural Library, since that Library is within U.S.D.A., it apparently could not require the cooperation of the National Library of Medicine, since that Library is within the Department of Health and Human Services.

Numbers (1), (7), (11), (13), and (14) apparently could not be implemented without additional legislation. This is because the matters included in these numbers would change existing law or affect courts or other agencies over which the U.S.D.A. has no jurisdiction. Specifically, to change a definition enacted by Congress, to authorize states to promulgate standards, to require other agencies to suspend or revoke federal support, or to establish crimes or causes of action would be to change the Act, not to implement it.

Henry Cohen
Legislative Attorney
American Law Division
October 24, 1984

Addendum: Section 13(a) of the Animal Welfare Act provides: "Nothing in this chapter shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to design, outlines, guidelines, or performance of actual research by a research facility as determined by such research facility." This might limit the Secretary's power to implement (4), (5), and (6).

STATEMENT BY SENATOR BOB DOLE
HOUSE SUBCOMMITTEE HEARINGS ON ANIMAL WELFARE

A TIMELY CONCERN



THANK YOU CONGRESSMAN BROWN; IT IS A PLEASURE TO BE HERE TODAY AND PRESENT TESTIMONY ON BEHALF OF THE SENATE ON LEGISLATION FOR THE HUMANE TREATMENT OF ANIMALS. I'M PLEASED THAT YOU INTRODUCED H.R. 5725, WHICH IS SIMILAR TO S. 657 WHICH SENATOR MELCHER AND I, ALONG WITH SEVERAL OTHER SENATORS, INTRODUCED MARCH 2ND, 1983 AND WHICH NOW HAS OVER 25 COSPONSORS IN THE SENATE. I WOULD STATE FOR THE RECORD THAT THE CHANGES INCLUDED IN THE HOUSE BILL ARE ACCEPTABLE TO ME.

ACTIONS, NOT WORDS

AS I HAVE OFTEN SAID TO AUDIENCES INTERESTED IN OBSERVING CONGRESS, "DON'T LISTEN TO WHAT WE SAY, BUT WATCH WHAT WE DO," BECAUSE OUR ACTIONS SPEAK LOUDER THAN OUR WORDS. THE SAME IS TRUE FOR THE MEDICAL COMMUNITY AND THE ANIMAL WELFARE COMMUNITY. THE SAME APPLIES TO SOME FARM INTERESTS WHO ARE NOT AT ALL AFFECTED BY THIS LEGISLATION, BUT WHO HAVE NEVER THE LESS LOBBIED AGAINST IT. OUR LEGISLATION IS AN AMENDMENT TO THE ANIMAL WELFARE ACT WHICH HAS A SPECIFIC EXEMPTION FOR FARM ANIMALS.

MR. CHAIRMAN, THERE WILL BE DETAILED TESTIMONY PRESENTED TODAY ON BOTH THE MERITS AND THE NEED FOR THIS LEGISLATION. BUT THERE ARE THOSE WHO SAY "WE BELIEVE IN THE HUMANE TREATMENT OF ANIMALS, BUT..."

AND YET AT EVERY CORNER TRY TO BLOCK RESPONSIBLE LEGISLATION. IT IS A NARROW VIEWPOINT THAT MAINTAINS THAT OUR PRESENT SYSTEM IS BASICALLY WITHOUT FAULT AND THAT TIGHTENING REGULATIONS TO PREVENT ABUSES SHOULD NOT BE ATTEMPTED.

SOME HAVE QUESTIONED THE NEED FOR LEGISLATION SUGGESTING THAT ABUSES ARE INFREQUENT. HOWEVER, MATERIAL OBTAINED UNDER THE FREEDOM OF INFORMATION ACT SHOWS THAT ABUSES ARE A COMMONPLACE PROBLEM EVEN IN SOME OF OUR MOST PRESTEGIOUS INSTITUTIONS. I SUGGEST THAT IT IS TIME TO STOP WAVING THE BANNER ENTITLED "NO LEGISLATION" AND PUT ACTION IN PLACE OF WORDS TO ENSURE THE PUBLIC THAT AMERICA HAS AN ADEQUATE ANIMAL WELFARE SYSTEM.

LET'S ASSURE THE TAXPAYERS WHO SPEND BILLIONS OF DOLLARS EVERY YEAR FINANCING MEDICAL RESEARCH THAT SAFEGUARDS NECESSARY TO PROTECT ANIMALS FROM ABUSE ARE IN PLACE. LET'S ALLOW PUBLIC INVOLVEMENT THROUGH INSTITUTIONAL COMMITTEES AND REQUEST PERIODIC INSPECTIONS. LET'S TAKE A UNITED AND SERIOUS LOOK AT HOW BETTER AND PRACTICAL ALTERNATIVES CAN POSSIBLY REDUCE THE NUMBER OF ANIMALS USED OR AT LEAST REDUCE THE PAIN THEY EXPERIENCE.

RESPONSIBLE LEGISLATION

MANY, MANY HOURS HAVE BEEN SPENT IN CONSULTATION WITH THE MEDICAL COMMUNITY AND THE ANIMAL WELFARE COMMUNITY IN AN EFFORT TO DEVELOP A BILL WHICH ADEQUATELY REFLECTS THE LEGITIMATE CONCERNS OF ALL

INVOLVED. WE HAVE EVEN INCLUDED FARM INTERESTS IN OUR DISCUSSIONS TO BE SURE THEIR INTERESTS ARE TAKEN INTO ACCOUNT. SEVERAL FARM GROUPS HAVE DECIDED TO REMAIN NEUTRAL BECAUSE THEY REALIZE THIS LEGISLATION DOES NOT AFFECT THEM.

THE SIGNIFICANT ROLE ANIMALS PLAY IN IMPORTANT RESEARCH AND TESTING AND THE VALUE THAT SUCH RESEARCH AND TESTING ADDS TO OUR SOCIETY IS GENERALLY RECOGNIZED. YET, EVERYONE AGREES THAT RESEARCH ANIMALS SHOULD BE TREATED HUMANELY SO THAT TEST RESULTS CAN BE ACCURATE AND TAXPAYERS' DOLLARS CAN BE SPENT IN A COST EFFICIENT MANNER. UNFORTUNATELY, WE HAVE NOT YET LEGISLATED A SYSTEM TO MAKE THIS TRUE.

MR. CHAIRMAN, THIS IS A MODERATE AND REASONABLE BILL AND IT IS TIME IT BE ENACTED.

American Society of Mammalogists

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24 September 1984

Honorable George E. Brown, Jr.
Chairman, Subcommittee on Department
Operations, Research, and Foreign Agriculture
Room 2256 Rayburn
Washington, D.C. 20515

Dear Congressman Brown:

As representatives of the American Society of Mammalogists, a professional society of over 3700 members, we had hoped to present testimony concerning the Improved Standards for Laboratory Animals Act, H.R. 5725 at the public hearing on 19 September 1984. Because of the time constraints of the hearing and the large number of witnesses already scheduled, we were not able to present testimony at the hearing. We would, however, ask that the attached testimony be included as part of the written hearing record. We would appreciate receiving a copy of the hearing record when published.

One of us (RCD) did attend the hearing and we will continue to monitor this legislation as it progresses. We would appreciate the opportunity to comment on this bill at a later time if necessary and thus would like to be kept informed by your staff of future action on this bill.

Thank you for this opportunity to submit this written statement of our viewpoints on H.R. 5725.

Respectfully,

Hugh H. Genoways
President
American Society of Mammalogists

Robert C. Dowler
Chairman, ASM Committee on
Legislation and Regulations

HHG/kk
Enc.

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Statement of Dr. Hugh H. Genoways, President, American Society Mammalogists and Dr. Robert C. Dowler, Chairman, ASM Committee on Legislation and Regulation for the written record of the hearing of the Subcommittee on Department Operations, Research, and Foreign Agriculture concerning H.R. 5725, the Improved Standards for Laboratory Animals Act.

The American Society of Mammalogists is a professional society representing over 3700 mammalogists worldwide with a majority of our members being from the United States. This society actively promotes research on mammals in the interest of advancing knowledge in all fields of biology.

The American Society of Mammalogists fully supports the humane care and treatment of all animals. However, we cannot support the passage of H.R. 5725 as written. In general, many of our comments below are concerned with the broad limits of coverage and undefined terminology used in H.R. 5725.

Many mammalogists conduct biomedical research in a laboratory setting, but a large proportion conduct field studies of wild animals that may involve such activities as collecting mammals taking routine measurements and blood samples, holding animals for various short term observations, tagging or marking animals for later identification if recaptured, attaching radio transmitters to animals to monitor their activities and movements and releasing them where captured. Such field situations are not generally considered to be "laboratories". There is, in fact a tendency to separate laboratory biologists and field biologists as somewhat distinct groups of research scientists. Although the title of H.R. 5725 is "the Improved Standards for Laboratory Animal Act" and the act is presumed to be aimed primarily at laboratory species used in biomedical research, a broad interpretation of wording in several sections could have an effect on field based research such as that described above, in addition to any effects on mammalian research in laboratories. The following specific comments are concerned with aspects of H.R. 5725 that would affect mammalogists conducting research in both laboratories and in field situations.

The requirement for establishment of an animal research committee to inspect "at least semiannually all animal study areas..." p. 7 lines 7-8) is essentially unworkable in most field research. A given "animal study area" may be a desert site in Arizona, a remote forest in Alaska, a river bank in Tropical forests of Peru, or a mountain side in India. Such study areas may or may not have formal structures may be utilized for time periods of a year or less, and are often used only once. Requiring a research facility to have such areas inspected by an animal research committee semiannually would be prohibitively expensive and we believe such requirements are not the intent of this act.

We are further concerned that many terms used in H.R. 5725 are either undefined or cannot be adequately defined. References to "pain" and/or "distress" are made throughout the text but neither have been defined, to our knowledge, and in reality they represent a continuum that occurs as a matter of degree. Even among human subjects what represents pain to one, may be imperceptible to another. This is not to suggest that painful procedures do not occur, but simply that judgement as to whether certain procedures are painful is often times subjective. For example, does taking blood samples, giving routine injections, or tagging animals cause pain? If judged to cause pain under this act such procedures would require consultation with a veterinarian (p. 5, lines 11-12) and involvement of the animal research committee (p. 7, lines 9-11).

Another term that appears to be undefined is "major operative procedure" (p. 6 line 2). Again, if loosely defined, what is considered a major operative procedure to a member of the committee representing community interests may not be "major" to the research scientist. Does amputation of a small animal's toe constitute a major operative procedure? If so, this might result in the animal being euthanized because it could not be used in any other major operative procedure in that or any other laboratory. Use of research techniques, such as artificial insemination, electroejaculation, caesarean section fetal transplants, or exutero embryo culture, intended to preserve or increase populations of a rare or endangered species might be impeded if considered to be major operative procedures.

Another provision of H.R. 5725 that would prevent many legitimate studies and increase the costs of others is that requiring separation by species (p. 4 line 1) Where wild animal species are brought into the laboratory for study, analyses may involve many different species. Providing facilities to house each wild species in a separate room (in addition to separate areas for standard laboratory animals) would be extremely expensive and often impossible to justify especially for smaller facilities at small colleges and universities. Such requirements should be made only when the potential for transmission of communicable health problems between the species in question has been demonstrated and/or is a potential threat.

In conclusion, we, as representatives of the American Society of Mammalogists, believe that the language of H.R. 5725 is too inclusive and ill-defined at this time and that passage of this act would impede and prevent legitimate research by mammalogists as well as other groups involved in biological research. We would be happy to work with the subcommittee in whatever way necessary to ensure that any legislation enacted is biologically sound. Thank you for this opportunity to state our views in H.R. 5725.

STATEMENT

Leon C. Hirsch, President
United States Surgical Corporation

on H.R. 5725

Before the
United States House of Representatives
Subcommittee on Agriculture

September 19, 1984

United States Surgical Corporation ("U.S. Surgical") is the leading producer of surgical stapling devices used to close wounds and reconstruct tissue during surgical procedures. Surgical staplers are standard equipment in operating rooms throughout the world and U.S. Surgical is continuing to develop new products and to refine our current devices.

U. S. Surgical is a research facility under the provisions of the Animal Welfare Act (the "Act") and takes its responsibilities seriously -- not just by meeting the standards of the Act, but by surpassing them. Our facilities are inspected by two Federal and two state agencies. In addition, we are accredited by "AAALAC", the American Association for Accreditation of Laboratory Animal Care, and take great pride in the excellent reputation of our medical facility.

We support efforts to assure humane treatment for laboratory animals; however, we are extremely concerned about amendments to the Act which can affect how we develop surgical devices. We are absolutely committed to patient

health and safety and believe it is absolutely essential to maintain our highly-specialized, technical salesforce to train surgeons and operating room personnel on complex surgical devices before the surgeons use them on human beings.

U. S. Surgical restricts the use of laboratory animals to the absolute minimum. We are extremely proud of the fact that we were the first medical device company to be issued FDA approval for performing a biochemical test as a substitute to using live animals in pyrogen testing.

Our sales efforts utilize illustrated encyclopedias, films and demonstrations on foam rubber organs by our specially trained salesforce. Live tissue is only used in limited circumstances: essential product development, testing under circumstances necessary to obtain government approval, and for training of surgeons, operating room personnel and our representatives. In this regard I want to make the following points:

1. Surgical devices must undergo the most rigorous testing procedures during development, including live tissue testing for chemical body reaction and hemostasis (control of bleeding). There is no method of testing for control of bleeding other than testing on live tissue.

2. Surgeons must be thoroughly trained, including live tissue experience, before using medical devices on humans. When surgeons and operating room personnel are ready to use our surgical stapling devices, we are committed to the highest level of training in order to assure patient safety and proper procedures. This live tissue training with surgical stapling devices is performed either in our laboratory or, by invitation, in the laboratories of a teaching university in conjunction with the faculty.
3. Medical teaching universities routinely call upon our highly trained technical salesforce to assist in the training of their residents and surgeons. Because of this, it is essential that we give our representatives adequate live tissue training in order to qualify them for teaching.
4. In addition to teaching surgeons on live tissue, our representatives are trained and qualified to be present in hospital operating rooms to provide technical product assistance to surgeons during actual operations. This is an important facet of our work and requires the highest level of training and a solid familiarity with hospital operating room procedures and etiquette.

U. S. Surgical, as a facility that has the full accreditation and certification of AAALAC, operates under animal care standards that far exceed the current statutory and regulatory "minimum" requirements. As stated earlier, we readily endorse the thrust of H.R. 5725. We wish the industry were free from violations or abuse, but recognize that sound laws are essential to assure humane treatment for laboratory animals. We believe that this objective is best obtained through legislation that rectifies problems or abuses where they actually exist. In this regard, we urge the Subcommittee to deliberate very carefully in considering H.R. 5725 in order to avoid any unintentional results which could hamper medical research, developing technology or essential training.

H.R. 5725 incorporates some specific improvements over its companion bill, S. 657. While I appreciate those adjustments, I still want to express my concerns to the Subcommittee. We have already discussed some specific language with staff, so I will merely highlight our concerns in this statement.

First, we believe it is important to provide the right incentive for facilities to voluntarily comply with or exceed the regulations and statutes. The federal government

simply cannot fully enforce all the provisions of the Animal Welfare Act and H.R. 5725 at all the animal research facilities. There are 3,300 research facilities across the country represented by 1,166 registrants (institutions or parent companies). In our opinion, any attempt to gain full compliance through enforcement alone is unrealistic and doomed to failure.

We urge the Subcommittee to adopt an approach which fosters voluntary compliance. Give research facilities which meet or exceed statutory standards a "safe harbor". Reward voluntary compliance with a corresponding reduction in burdensome paperwork and duplicative inspections. Make penalties harsher for those facilities which certify compliance but fail to maintain it -- creating an incentive to provide and maintain the highest level of animal care. There are several ways in which such incentives can be incorporated into H.R. 5725.

Second, we suggest there is an enormous distinction in the proprietary interests of government research and private industry and we are extremely concerned about the protection of trade secrets and other private proprietary rights under the provisions of H.R. 5725. Whereas in federally funded laboratories, information should be shared to reduce duplication and unnecessary animal use and expense, private laboratories are entitled to the exclusive rights in the fruits of their research and must assure complete confidentiality in order to protect their proprietary rights. We urge the

Subcommittee to consider carefully whether there is any need to include private research facilities in the proposed legislation. U. S. Surgical is currently subject to the inspection of two federal and two state agencies in addition to the more stringent requirements for AAALAC certification. We question whether an additional inspection by an institutional "animal research committee" is necessary, especially in light of the trade secrets-proprietary rights question.

We recognize the attempt made to provide safeguards against disclosure in H.R. 5725 but suggest that they ignore the greater problem that the presence of an outside person represents. Besides, it is unrealistic to require an outside volunteer to serve on an animal research committee and to be subjected to extensive criminal penalties for even inadvertent disclosure. Simply enacting stiffer penalties against disclosure is not the answer -- eliminating the potential problem of the outside member is the proper solution.

Section 4 of the bill requires at least one member of such a committee to have no association with the research facility and be primarily responsible for representing the community concerns regarding the welfare of animal subjects (page 6, lines 21-24). In private research facilities,

it is critical that certain business information be closely guarded, sometimes even from employees within the research facility. For example, in April, 1983, U.S. Surgical announced the development and marketing of the world's first absorbable surgical staple, representing a major surgical advance and an immense potential patient benefit. However, it was critical for competitive reasons that the mere existence of the project leading to this break-through be closely guarded. We are not convinced that bona fide trade secrets or confidential information of this kind would be adequately protected by the provisions of the bill. This kind of confidential information is the life blood of high technology industries and cannot be compromised.

We respectfully suggest that the best solution is to have the "animal research committee" provision apply only to research facilities receiving federal funds. This is reasonable in light of the number of federal and state inspections facilities face each year. At the very minimum, all research and development activities of a proprietary nature must be exempt from inspection by any outside member of an animal research committee. We welcome all government inspectors, but strongly object to outside people who are not government employees conducting inspections in our private facility. We do not object to the

inspection itself, but we do object to the potential compromise of our very basic and valuable rights that an outside member represents.

Lastly, during hearings in the Senate on S. 657 Senator Dole stated his intent that the bill not impose significant additional costs on research facilities. We submit that both S. 657 and H.R. 5725 will significantly raise the costs to research facilities which make a good faith effort to comply with all provisions. To the extent there are costs required to comply with H.R. 5725, they will be passed on somewhere. Federally funded research facilities will ultimately pass those additional expenses through as an increased cost of research and they will be borne by the taxpayer. In private research facilities, the cost can only be passed on to the consumer. This Subcommittee has a duty to evaluate the real cost of H.R. 5725 and assure that the legitimate intent of the legislation does not impose any more nonproductive costs than absolutely essential.

In conclusion, we share the Subcommittee's concern for assuring proper treatment for laboratory animals. We believe our own facility far exceeds statutory and regulatory requirements and we invite the Committee and its staff to visit our laboratory in order to see first hand a private research facility covered by the Animal Welfare Act.

We are available to work with the Subcommittee to develop legislation which addresses our concerns in a fair and equitable manner while also assuring proper treatment for laboratory animals.

AMERICAN SOCIETY FOR PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS

9650 Rockville Pike

Bethesda, Maryland 20814

301-530-7060

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September 18, 1984

Honorable George E. Brown, Jr.
 Chairman, House Agriculture
 Subcommittee on Department Operations
 Research and Foreign Agriculture
 U.S. House of Representatives
 2256 Rayburn Building
 Washington, DC 20515

Dear Mr. Chairman:

The American Society for Pharmacology and Experimental Therapeutics is appreciative of the opportunity to comment on HR 5725. We welcome the concerns expressed by the authors and supporters of HR 5725 for the quality of life of animal subjects. We, by example, have insisted upon and practiced care and consideration for animal subjects without the need for excessive regulatory pressures. We contend that additional restrictions that exceed the present requirements embodied in the Animal Welfare Act are not warranted. We urge and support the recommendations of the Federation of American Societies for Experimental Biology that congressional efforts be focused on a fact-finding study concerning research, testing and education involving the use of animals. A study conducted by a prestigious body such as the National Academy of Sciences would separate polemics and confrontational hyperbole from the specific issues of providing the best care, environment and protection for animal subjects.

Sincerely yours,



Marjorie G. Horning
 President, ASPET



Keith F. Killam
 Chairman, Committee on
 Professional Affairs

Enclosure

JOURNALS: The Journal of Pharmacology & Experimental Therapeutics, Pharmacological Reviews, Molecular Pharmacology, The Pharmacologist, Rational Drug Therapy, Clinical Pharmacology & Therapeutics, Drug Metabolism & Disposition

Linda H. Huber
30 Sea View Avenue
Piedmont, Ca. 94611

September 17, 1984

To Members of the Subcommittee on Department Operations, Research and Foreign Agri.:

Re: H.R. 5725

My name is Linda Huber, and I am a member of Californians for Responsible Research, Fund for Animals, Animal Welfare Institute, Animal Protection Institute of America, People for the Ethical Treatment of Animals (PETA) and other organizations. In active affiliation with the Animal Rights Direct Action Coalition, I have become informed of the University of California's Berkeley Campus violations of the Animal Welfare Act with documented deficiencies in the humane handling, care and treatment of animals - specifically USDA citations from late 1979 to January, 1984 for inadequate disease control, inadequate veterinary care, inadequate animal care and inadequate identification of animals.

A recent KCBS radio editorial broadcasted the case of a male primate suffering from necrotic and gangrenous skin in the perineal area, entire scrotum, feet and ears. In a letter dated 2/20/79 to Dr. DeValois (Professor, Psychology Department) from David H. Sesline (D.V.M., Senior Veterinarian, Laboratory Animal Medicine), he writes, "This animal was in such discomfort that he could not climb to the lixit to drink and was observed by the animal technicians and myself to attempt to drink his own urine...I urge you to observe your animals frequently or supervise those who do..."

Despite the existence of a Committee for the Protection of Animal Subjects (CPAS established 1982), the University was fined \$12,000 in April, 1984 by the USDA. This same committee is on record as being against legislation designed to improve or strengthen standards for animal care as documented in a joint report issued by Californians for Responsible Research and Buddhists Concerned for Animals called Animal Care and Animal Care Policy at University of California, Berkeley, Animal Research Facilities, October, 1983.

In consideration that the University has proved an unwillingness to care for its animal subjects in compliance with the Animal Welfare Act plus the realization that the USDA itself was delinquent in pressing a timely complaint/fine against the University - despite the long history of repeated violations - H.R. 5725 particularly addresses this type of situation with improved monitoring and reporting of laboratory animal conditions. Acknowledging that this University's (CPAS) peer review has failed, (information regarding the above primate was never provided the USDA), the presence of a community animal welfare representative on committee to guarantee enforcement of the Animal Welfare Act is critical. This as well as all other features of H.R.5725 demands enactment.

Sincerely,
Linda H. Huber
Linda H. Huber
Member, Californians for Responsible Research
attachment

"We have uncovered what appears to be a pattern of experimentation using animals which often produces no useful results other than mutilated or dead animals.

There seems to be a mentality that what goes on at the University is the University's business and no one else's, and it seems to be that the academic community is immune from the public, and the University will take care of its own problems, and that's the end of it."

Bob Jimenez, Newscaster
KRON-TV
July 7, 1982

"This is to inform you that it was necessary today to euthanize one of your primates which had apparently been severely injured for some time. I do not make a practice of euthanizing research animals without the concurrence of the investigator but in this case the necessity was obvious. This animal had been injured sometime (weeks?) ago ... The perineal area and entire scrotum were necrotic and gangrenous with full thickness skin death ... The animal was in such discomfort that he could not climb to the lixit to drink and was observed by the animal technician and myself to attempt to drink his own urine ... This animal could probably have been saved and his discomfort minimized if treated early."

David H. Sesline, D.V.M.
Senior Veterinarian
Laboratory Animal Medicine
U.C. Berkeley
Feb. 20, 1979

"It is increasingly obvious that while the campus veterinarian seems to have the authority to provide veterinary care, the Department of Psychology is ignoring or challenging the matter."

Veterinary Inspector
U.S. Dept. of Agriculture
March 5, 1980

"It would appear that cephalic electrode implantation and other experimental surgery is being done by researchers and graduate students by "on the job training" at the animals expense."

R. F. Van Gelder, D.V.M.
Animal Care Specialist
U.S. Dept. of Agriculture

"I remember seeing chronic brain implants with great amounts of pus oozing from between the skin and the bone wax. I remember monkeys kept in individual cages, exhibiting all sorts of neurotic behavior such as compulsive self-clutching and chewing off the fingers of monkeys in adjacent cages. I recollect a general ignorance or disregard for aseptic surgical technique. I recall the resistance of MOST investigators to making changes in basic husbandry or experimental methodology which would relieve animal suffering."

Bruce Max Feldman, D.V.M.
Clinical Veterinarian
U.C. Berkeley
1969-1980

"At the invitation of their director of animal facilities, Dr. Max Redfearn, I toured the present Life Science Building. I was appalled by the conditions I observed. Rooms in which animals were housed were substandard. Many rooms were filthy with feces, feathers and other debris on the floors ... Many of the rabbits I saw had filthy cages which had not been cleaned in several days; these rooms were malodorous. Turtles were housed in filthy water with no proper food or sunlight, and no place on which to haul out of the water. These particular turtles had had major abdominal surgery after which they had been placed in the filthy conditions I observed. Two large roosters were housed in cages so small that they could not stand upright; they were in poor bodily condition as well. A room in which major surgery was apparently routinely performed did not have any provisions for aseptic technique. Yet I was shown another room that had been designed for this purpose but had never been used, according to Dr. Redfearn."

Ned Buyukmihic, V.M.D.
Asst. Prof. of Ophthalmology
U.C. Davis
March 16, 1983

"Review of inspection reports, Sept. 7, 1983 to Dec. 1983 revealed repeated deficiencies, some repeated every month for the four months. Most of these reports are apparently ignored. This would indicate a lack of concern for proper animal husbandry and a poor attitude regarding compliance with not only USDA requirements, but also NIH and AAALAC standards by some researchers. And a lack of any authority on campus to take corrective action, or reluctance by the authority to take action on repeated deficiencies."

Horner E. Malaby, Jr. D.V.M.
Veterinary Medical Officer
U.S. Dept. of Agriculture
January 27, 1984

"This is to respectfully inform you that I am invoking the Appeals Procedure for Non-Senate Academic Appointees on the basis of arbitrary, capricious and unreasonable actions by senior administrative officers. ...Chancellor Heyman's statement in the press release of March 13, 1984, 'we need a type of expertise that we have up to now lacked ...,' is an incredible inexactitude and an outright insult to a member of the veterinary profession."

The series of events leading to my demotion I consider to be inexcusable, unprincipled and indescribably unconscionable."

Maxwell S. Redfearn, D.V.M., MS, Ph.D.,
Campus Veterinarian
U.C. Berkeley
March 26, 1984

"I am writing in response to your false, misleading, and insulting statements in the March 13th, 1984 press release from the UCB Office of Public Information."

You state: ... 'We need a type of expertise that we have up to now lacked — a professional guidance based upon thorough knowledge of all actions needed to meet AAALAC's requirements in the management of animal care.' Eight or so laboratory animal veterinarians have worked in the UCB Division of Animal Resources during the past 10 to 15 years. During the same period, other veterinarians have worked for or consulted with various campus departments as laboratory animal veterinarians. It is particularly inaccurate and insulting to imply that these veterinarians were ignorant of or could not comprehend AAALAC requirements, for they are basic and fundamental, not sophisticated or technical."

The problem of UCB laboratory animal care has always been a lack of will or interest on the part of those in authority. This inaction over a period of decades has resulted in the scathing reports on animal care to which the campus has been subject. It is appalling to see the University respond by making redundant personnel appointments and creating redundant committees."

Bruce Max Feldman, D.V.M.
Former Clinical Veterinarian
U.C. Berkeley
March 31, 1984

(From a letter to Ira M. Heyman,
Chancellor, U.C. Berkeley)

CALIFORNIANS FOR RESPONSIBLE RESEARCH

21 Tamal Vista Blvd.
Corte Madera, CA 94925
415/924-4454

Founded in May of 1983 by members of the veterinary, medical, educational, legal, and artistic communities, *Californians For Responsible Research* has grown in response to the waste, negligence, cruelty and dishonesty occurring within the research laboratories of the University of California.

Scandal and corruption occurring outside of the laboratory results primarily in monetary loss; when it happens within research laboratories, it is usually compounded by senseless pain, suffering, agony and death.

This flyer focuses on the problems involving non-human animals occurring within the biological and medical laboratories of the University of California. It will give you an overview of the problems we at CFRR are attempting to correct, and the reasons we believe it is essential that CFRR continue to act and grow.

Association of Professors of Medicine

J. WILLIS HURST, M.D.
President
Department of Medicine
Emory University
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(404) 585-3421

LYNN MORRISON
Special Assistant for
Policy Activities
1319 F Street, N.W., #1080
Washington, D.C. 20004
(202) 737-3911

September 25, 1984

Honorable George E. Brown
Chairman
Subcommittee on Department Operations,
Research and Foreign Agriculture
House Committee on Agriculture
1430 Longworth House Office Building
Washington, D.C. 20515

Dear Mr. Brown:

The Association of Professors of Medicine is the organization that represents the chairpersons of departments of internal medicine in the nation's medical schools. As chairman of the largest clinical departments, members of the Association have responsibility for a substantial portion of the teaching, research, and patient care programs of these institutions.

We understand that your Subcommittee recently held hearings on H.R. 5725, the "Improved Standards for Laboratory Animals Act." We respectfully submit the enclosed statement and the attached brochure for inclusion in the hearing record.

Thank you for considering our views.

Sincerely,

J. Willis Hurst, M.D.

J. Willis Hurst, M.D.
President

cc: Members, Subcommittee on Department Operations,
Research and Foreign Agriculture

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STATEMENT OF THE ASSOCIATION OF PROFESSORS OF MEDICINE REGARDING ISSUES RELATED TO THE USE OF ANIMALS IN RESEARCH AND TESTING

LYNN MORRISON
Special Assistant for
Policy Activities
1319 F Street, N.W., #1080
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(202) 737-3311

The Association of Professors of Medicine (APM) is the organization that represents the chairpersons of departments of internal medicine in the nation's medical schools. The individual members of APM have direct responsibility for a substantial portion of the teaching, research, and patient care programs of these institutions. We would like to offer our general views regarding the use of animals in research and testing as the Agriculture Subcommittee on Department Operations, Research and Foreign Agriculture begins its consideration of H.R. 5725, the "Improved Standards for Laboratory Animals Act."

As physician scientists extensively involved in the conduct of biomedical research, members of APM are keenly aware of the essential role of laboratory animals. As noted in the attached brochure, animals are used as substitutes for humans in research regarding the diagnosis, treatment and prevention of human disease. Virtually every major advance in medical science has depended upon research involving animals. The following are just a few examples which demonstrate how knowledge gained from animal research has enabled millions to lead longer, healthier lives:

- the development of insulin - In 1923, Drs. Frederick Banting and John Macleod were awarded the Nobel prize in physiology and medicine for research involving dogs which lead to the development of insulin. There

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are in the United States alone approximately 11 million diabetics, most of whom live normal lives with the aid of insulin injections. Previous treatment for diabetes consisted of starvation diet to delay, however briefly, the inevitable death of the patient.

- the development of the polio vaccine - The polio vaccine, developed through research involving animals, has resulted in the almost total eradication of the disease. Prior to 1955, polio victimized in this country alone approximately 30,000 people each year--most of them children.
- improved cancer therapies - As a result of the development of chemotherapeutic drugs which are evaluated in animal models, increasing numbers of young and adult victims of cancer are being treated successfully. The National Institutes of Health estimates that 17,411 fewer children died of the disease between 1965 and 1979 than expected at the 1950 rate. A related development is improved treatment for Hodgkin's disease, which is most common among the 15-34 age group. Thirty-five years ago, this malignancy was considered incurable. 1980 statistics revealed the cure rate to be approximately 73%
- the pump oxygenator - Without this device, which maintains the circulation and oxygenation of the blood when the heart is stopped, life-saving surgical procedures for the heart and major arteries could not have been developed. Coronary bypass operations, which extend the lives of over 150,000 people each year in the United States, could not be performed. The pump oxygenator was developed in the 1950's by teams of researchers working here and in Great Britain. However, initial testing on dogs, pigs, and calves was performed in this country because of the British government's restrictions on the use of laboratory animals.

These are just a few of the numerous examples of how mankind has benefitted from research involving animals. In addition, animals are used to determine the safety and efficacy of drugs and vaccines prior to their approval for use in humans. It is also important to note that animals are used in research to improve veterinary care for pets and livestock.

The Association of Professors of Medicine strongly supports the humane use of animals in biomedical research and testing. Along with the general public, we are appalled by any abuse of animals--whether in a scientific, industrial or sporting environment. For humanitarian reasons, and in the interest of scientific integrity, the Association believes that it is imperative for laboratory animals to receive appropriate care and treatment. Fortunately, as noted in the attached brochure, the humane treatment of animals used in research is almost always assured by scientists themselves. In addition, most research institutions maintain committees to inspect animal care facilities and actively oversee the use of animals for scientific purposes. In terms of external controls, the Federal government has established standards for laboratory animal care and facilities are inspected by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture to assure compliance with these standards.

Despite the essential role of laboratory animals and the safeguards that exist to assure their appropriate use, there are those who suggest that research involving animals is inhumane and unnecessary. Some advocate legislation that would severely limit or totally prohibit the utilization of animals for scientific purposes. Others support the modification of existing laws regarding the care and treatment of laboratory animals. The Association of Professors of Medicine would like to call attention to the fact that there is a striking absence of data to suggest that these proposals are warranted. At present, there is simply insufficient information available

to make an informed determination of the need for--much less the content of--such legislation. This view is supported by a 1980 report of the General Accounting Office stating that, "...more information is needed on the advantages and limitations of alternative methods and the extent of inappropriate animal experimentation before deciding whether legislation...is needed."

Accordingly, the Association is on record in support of proposals which advocate a Congressionally-mandated 18-month study of the use of animals in research and testing. A study by the National Academy of Sciences (NAS) of issues related to the care of laboratory animals and the development of non-animal methodologies would provide a much-needed data base on this subject. The Association has urged the Congress to authorize an NAS study and await the results of this effort prior to proceeding with additional--potentially premature or unnecessary--legislation regarding this important issue. Until the results of such a study are available, the Association can not offer its support for additional legislation related to the use of animals in research and testing.

In addition to advocating a study, the Association has encouraged the Congress to provide adequate appropriations for the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). Under the auspices of this agency, animal care facilities are inspected by highly qualified veterinarians and other animal health experts. Unfortunately, in recent years the efficiency of APHIS has been hampered by insufficient funding. The Association believes that the objective of assuring the humane care of laboratory animals can be achieved most effectively if the Congress provides increased levels of support for APHIS programs. In addition, we suggest that the enactment of new legislation relevant to APHIS activities may prove ineffectual so long as funding limitations constrain the agency's ability to function.

In summary, at present the Association of Professors of Medicine can not support the enactment of legislation regarding the use of animals in research and testing. Instead, the Association urges the Congress to:

- authorize an 18-month study by the National Academy of Sciences of the use of laboratory animals, and
- provide sufficient appropriations for the Animal and Plant Health Inspection Service so that thorough inspections of research facilities can be performed.

The Association firmly believes that these steps should be taken before the Congress proceeds to enact additional legislation.

(The brochure is held in the committee files.)

National Society for Medical Research

TO PROMOTE PUBLIC UNDERSTANDING OF THE PRINCIPLES AND HUMANITARIAN
GOALS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

September 11, 1984

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Ms. Sara Rasmussen
c/o Rep. George E. Brown, Jr.
2256 Rayburn House Office Building
Washington, D.C. 20515

Re: H.R. 5725

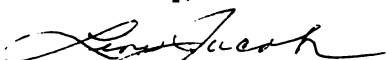
Dear Ms. Rasmussen:

We understand that Rep. Brown is planning hearings on the subject bill (H.R. 5725) for 19 September 1984.

The National Society for Medical Research has been working for 38 years to provide the public and the Congress with information on the importance of animals in biomedical research. We have recognized the importance of responsible care in the handling of research animals and have advocated awareness by scientists of the need for such care. On the other hand, we have cautioned against unnecessary restrictions of research.

We would like to have an opportunity to have our views presented at the hearings. In discussions with the Association of American Medical Colleges on this subject we have learned the AAMC has already applied to you for an opportunity to present its views, and we have found that those views of the proposed legislation are consonant with our own. In the interest of preserving the time of the committee, therefore, we wish to suggest that the AAMC representative be heard and that his/her testimony be understood to be endorsed also by NSMR.

Sincerely,



Leon Jacobs, Ph.D.
Scientific Consultant

cc: John F. Sherman, Ph.D., AAMC
Melissa Brown, AAMC



September 19, 1984

TESTIMONY IN FAVOR OF H.R. 5725

The Honorable George E. Brown, Jr.
Chairman
Subcommittee on Department Operations, Research and
Foreign Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Brown:

PAWS represents more than 10,000 people who believe that this Congress has a moral obligation to pass H.R. 5725. When you are spending some four billion dollars of our tax money on animal research every year, you ought to have the basic decency to provide for the humane treatment of those animals.

So far, Congress has failed in its moral responsibility to do this, and millions of animals have paid a terrible price in suffering as a result.

H.R. 5725 will not stop all cruel experiments, but it will be the first step in that direction-- a step that should have been taken before the first dollar was ever appropriated for any kind of research on live animals.

Thank you for holding hearings on this long overdue legislation.

Sincerely yours,

Jennifer Johnson
Chairman
PAWS Legislative Committee

SEP 24 1984

Non-Profit Humane Organization Since 1987

PROGRESSIVE ANIMAL WELFARE SOCIETY
Humane Education & Animal Care Center
P.O. Box 1037
Lynnwood, Washington 98046
(206) 743-5845 778-0881



TUFTS UNIVERSITY

Jean Mayer
President

September 12, 1984

The Honorable George E. Brown, Jr.
U. S. House of Representatives
2256 Rayburn House Office Building
Washington, D. C. 20515

Dear Congressman Brown:

Re: H. R. 5725

I want to congratulate you and Senator Dole on the development of a useful and sensible bill on standards for animal experimentation.

It is difficult for those of us who both care about animals and are committed to the need for animal experimentation in biomedical research to maintain a position which is acceptable to the majority of our fellow citizens and is not constantly attacked both by scientists who see any regulation and any protection of animal rights as a reflection on their integrity and by radical "antivivisectionists" who would eliminate animal experimentation altogether.

I think you have succeeded in this difficult task, and I think your bill deserves to be supported and passed.

Sincerely yours,

cc: Senator Robert Dole

Medford, Massachusetts 02155
(617) 381-3300



Dear Members of Congress

I'm a young black male who grew up in the inner city of Washington D.C., but frequent trips during my youth to places where nature flourished has given me great appreciation for our environment and the animals within it. The fact that I realize the great need for people to assume their role as protectors of this environment is directly related to this. In response to this realization I have been attempting to establish an organization called The Replenishment of Endangered Species Conservation Union (RESCU) in order to put to work some ideas I have for this purpose.

I've been working at the Armed Forces Institute of Dental Research (U.S.A.I.D.R.) for the last year where I've been witness to a large amount of misuse of animals in the name of research. People at this institute gained knowledge of my interest to save animals and saw me as a threat to their progress. I'm now being railroaded out of my job here because I'm suspected of making a recent report to the American Society for the prevention of cruelty to animals of experimentation being done on rabbits here at U.S.A.I.D.R.

That fact that I can write a letter such as this to be read, by the entire United States Congress is evidence that mankind is beginning to awaken to his selfishness. There has always been individuals who cared enough to want to do something about man's mistreatment of the animals kingdom, but we've made up such a small portion of the world's population that we couldn't begin to effect the minds and ways of the vast majority. Even still today, we lack the ability to bring about an abrupt change due to the sensitive and peaceful nature of our being. You see it's this sensitive nature that we possess that allows us to feel for these animals, and it is also this sensitive nature that is needed to bring forth peace in the world. So you must listen to us now before I and those like me become extinct like so many forms of life before us that were unable to survive in a changed environment not suitable for their existence.

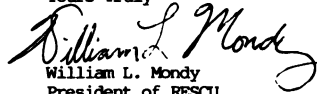
I'm dumbfounded by the true meaning behind the upcoming hearing for animals rights in America. To pass legislation that guarantees the up keep and concern for pain of animals used for experimentation is like the laws passed in the 1800's protecting slaves from mistreatment. It takes all the power within me to keep from giving up on the in power of the world today. I thought that Congress was finally about to do something good. But the truth of the matter is that Congress is only scimming the surface of an injustice that needs to be scooped up whole and thrown out as we do with radio active waste. For the product of this needless research has more of a detrimental effect of people than it does them good.

With our animal experimentation we discover more things to be afraid of dying from rather than excepting the fact that we all must die. We can't change that fact and the more we try, the more causes of death we find. Now we can anticipate but we can't prevent it. We discovered that Cancer can cause death but we can't find, nor will we ever find a way to cure it. The more we discover the more we find there is to discover. Cancer has been around since life itself, and by discovering Cancer we discovered something to make our life more fearful not prolonged.

Man has a tendency to think of animals as being inferior to him. This is because a man has the natural instinct to think of himself better than any other, but just because we think this doesn't make it so. We are no more important to this worlds ecosystem than the giant redwood tree. We have no more control over our existence than does a tiny protozoa. We have been for ages trying to find ways to increase our life span by scientific research, but even today when we have advance far in these areas, the most primitive scientifically advanced civilization have been more content, more harmonious, and longer lived than the so called advanced civilizations. Yet we called these people primitive. We call these people savages, because they fight and continue to fight modern mans attempts at distruping their freedom and their harmony with nature. We saw this in the Indians long past gone, we saw this in the Africans sold into slavery, we saw this in the animals that have been domesticated for mans benefiits, we see this still today in their children and our children as well. We rebel against modernization not because we aren't intellegent not because we aren't educated, but because we have something within us, something that within us all, something described as God by some as instinct by others, but we all must agree that what ever it is it gives us great will to be untamed by mankinds desire seize all things he admires. Like Abraham Lincoln knew when he wrote the Gettysburg Address, I too know that the world will little note nor long remeber what I say here, but I hope some one will here my cry for freedom, not just for myself but for all life great and small and help me reach my God given goals.

Soon I too may no longer be able to maintain my free will because of my need to survive. I must maintain my free will or die trying, or maybe some one will read this letter and come to my RESCU just as I seek to rescue others with a desire to be free. I soon will be without emplovment because some people find my will to be free, and my desire to help things in need something to be jelous of, and thus seek to destroy me, but I have faith that some will come to my RESCU and help me find a way to save whats left of the free world from mankinds desire to control all things he admires, and that have the will and the right to be free.

Yours Truly



William L. Mondy
President of RESCU
4726 9th St. N.W.
Washington D.C. 20011

Submission of
 Our Animal WARDS
 2225 Observatory Place, N. W.
 Washington, D. C. 20007

COMMENTS on H.R. 5725
 THE IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT
 presented to the
 Committee on Agriculture Subcommittee on Department Operations,
 Research, and Foreign Agriculture

We are grateful for this hearing. It proves that the shameful conditions for animals in research have begun to be examined again because the Subcommittee believes complaints of the present system are valid. In assessing what needs to be done, it is necessary to evaluate USDA-APHIS service for its usefulness in improving the care of animals in research.

We believe that USDA is only partially to blame for the present inadequacies in the inspection program, its staffing, and the failure to require necessary improvements by the laboratories. In 1966 when USDA reluctantly accepted responsibility for policing the care of animals in research, we remember the struggle of the Secretary of Agriculture to resist the new assignment. Eighteen years have proved that he was right. However, at that time, USDA had agents across the country, and the plan seemed logical.

In retrospect, some factors were overlooked. We failed to anticipate that the medical establishment would be so insistent on, and successful in, maintaining the status quo for animals in research. Periodic inspection is unwelcome in many areas, and possibly USDA's difficulty could have been predicted. As a result of USDA's lack of success in effecting change, only a minority of the research centers are maintaining animal care standards set by the Public Health Service. We believe responsibility for

laboratory animal care should lie with PHS and the local Animal Care Committees. PHS has to be vitally concerned in this area because research funds for the National Institutes of Health have grown from \$1-billion in 1971 to \$5-billion. The research community should accept the standards for care already outlined by PHS, and research professionals should insure that their research centers not fall below those standards. There is growing advocacy for decent care and concerns on the inside of research, backed by indignant pressure from the public, as reflected in press accounts of inspection inadequacies.

As an example of a new sense of responsibility, NIH has taken its first steps to GO AND SEE conditions in ten of its research centers under very restricted circumstances. It is logical and incumbent on PHS and NIH to be responsible for resources they allocate. To know the facts is NIH's real duty in facing the situation. Continuing USDA inspection of research centers is ineffective and sometimes duplicative of NIH services, which should clearly be PHS's sole responsibility. For eighteen years, USDA has engaged in hit and miss activity in this area, and now in ten brief visits, NIH has made some important observations of where constructive changes should be made.

The inspection service of USDA for laboratory animals was established in 1966, and Section 13 of the Animal Welfare Act mandated a veterinary service in each research center. It was understood that these professional men and women were not to interfere with research but rather were to improve the environment of the animals and to advise better ways to avoid animal suffering. This is an invaluable service when it is clearly understood as an integral part of the established medical protocol with no implication of policing. It should be reemphasized for the practical organization of

care in local research centers.

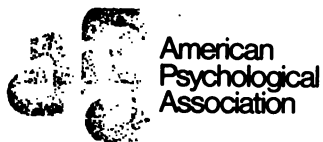
H.R. 5725 would duplicate the establishment of local Animal Care Committees initially proposed in the Walgren bill in 1981. That bill included the two essentials for relief of suffering of animals in laboratories -- a clear system of care to avoid all possible stress and the use of alternatives when possible. Probably all that is acceptable in this area at this time has already been approved by the House as an amendment to the Waxman bill, now stalled for lack of a Conference Committee hearing. We believe the Walgren proposal for mandatory Animal Care Committees in each research center is an essential way to have responsible recognition of the problems involved in professional handling of animals in research.

Another element of this legislation which duplicates activities already existing, is the proposal to create an information center for research in USDA. The five divisions of PHS, which includes NIH, already have the largest accumulation of facts about animals in research in this country. The need to coordinate such information to make it more useful is an important goal. USDA and other agencies of Government should recognize the economy of creating a single information center through a joint project in PHS in coordination with the National Library of Medicine.

In short, USDA has an impossible set of responsibilities. Besides its authority over dealers, exhibitors, auctions, and transportation -- where its power is more acceptable -- research coverage has been added. Effective work with research centers requires a differently equipped agent and strong national relish for the job. These are lacking in USDA. We believe research coverage should be under PHS rather than USDA.

We have urged USDA to take the position that the Animal Welfare Act can best be strengthened by assessing the services which can be most effectively assumed with its limited funds, and then to clarify its organizational program to accomplish the assignment. Certainly one area where USDA has been overburdened inappropriately is the reform of care for animals in research.

Since 1953, WARDS has searched for a way to spare suffering for animals in research. We hope this Subcommittee will see some merit in our new approach to change the duplicative system which results in unnecessary animal torture and adversely affects research findings.



TESTIMONY OF
Michael S. Pallak, Ph.D., Executive Officer
AMERICAN PSYCHOLOGICAL ASSOCIATION

Before the
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH,
AND FOREIGN AGRICULTURE

COMMITTEE ON AGRICULTURE
UNITED STATES HOUSE OF REPRESENTATIVES

On the subject of

H.R. 5725, THE IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT

The Honorable George E. Brown, Jr.
Chair

September 19, 1984

SUMMARY

- o The American Psychological Association recommends to the House that, before any animal research legislation is enacted, a study be conducted as proposed H.R. 2350, The Health Research Extension Act. We believe it is necessary to address the numerous unanswered questions surrounding the use of animals in research in order to make effective and appropriate policy decisions in this area.

- o With regard to H.R. 5725, we believe that many provisions would increase the regulatory burden for researchers without necessarily improving animal welfare, and that this legislation may pose particular problems for behavioral research, which often cannot use alternative research subjects.

Mr. Chairman, and Members of the Subcommittee:

My name is Michael S. Pallak. I am Executive Officer of the American Psychological Association (APA) representing 72,000 research and clinical psychologists. Thank you for the opportunity to comment on H.R. 5725, the "Improved Standards for Laboratory Animals Act" (Brown, D-CA). A substantial number of APA's members are behavioral researchers whose studies involve animals.

The provisions of H.R. 5725 affect the whole range of animal experimentation from medical vivisection, to psychological observation of animals, to experiments in animal husbandry. While we are in full agreement with the bill's stated purpose -- "to ensure the proper treatment of laboratory animals" -- we are concerned that some of the proposed mechanisms would create expensive and unnecessary bureaucratic interference in animal research programs in hospitals, university research facilities and agriculture experimental programs.

The American psychological community concurs with the general objectives of the proposed animal research legislation. However, we are concerned that there is insufficient information on which to judge whether the mechanisms set forth in this legislation will have the desired results. We believe it is essential to assess the impact of these bills on productive research that is of critical importance to human welfare as well as their impact on animal welfare.

One particular concern for behavioral researchers is the fact that alternative methods of studying behavior for the most part are not feasible. Studying behavior requires studying live animals. Restrictions on the use of human subjects in research compel the use of other animals. The quality and momentum of this research have profound implications for human health and well-being.

Current research methods are not immune to improvement or change, but there must be a sound basis for rejecting them. The fact that alternatives are not now being used en masse does not signal a lack of awareness or sensitivity on the part of the research community. It may well reflect the necessarily slow process of developing such alternatives.

We believe that legislation such as H.R. 5725 will not be effective unless it is based on something more than assumptions about what will or will not improve the care and welfare of laboratory animals. A study, such as that proposed in H.R. 2350, the Health Research Extension Act, will produce accurate information about the number and type of animals being used, and about existing administrative and research practices that affect their welfare. Only with this information will the most effective and appropriate policies and legislative mechanisms be developed for animal research.

Our comments on H.R. 5725 follow.

Alternatives to the Use of Animals

In several instances, H.R. 5725 promotes the use of alternative methods of research or alternative research subjects. We support the objective of minimizing the number of animals being used, and minimizing any discomfort experienced by animals that are used. However, the emphasis on alternatives poses a problem for behavioral science in particular because alternatives are not as readily available for the study of behavior as they may be in other areas of science.

Tissue cultures, computers and radioimmunoassays are often suggested as replacements for animals. We believe that many researchers in a variety of disciplines would prefer to use these adjunct methods, but substitutes such as laboratory cultures of cells, while useful for certain biological and medical tests, do not develop arthritis, heart disease, multiple sclerosis, mental disorders or drug addiction. Tissue cultures cannot be used to study the interactions or behavior of body organs -- for example, the effects of cardiovascular changes on brain function or kidney physiology. It is virtually impossible to study the behavior of a whole organism through the use of alternatives.

Despite these difficulties, behavioral as well as biomedical researchers are in active pursuit of alternatives to using laboratory animals. Alternatives are sought as a matter of routine in research, and their use is stressed whenever possible. However, this legislation offers little protection for research that cannot use alternatives to animals. Our concern

is that such research would be subject to unnecessary delays or even unjustified rejection in federal review and funding processes. Problems caused by the demand for alternatives would be magnified for behavioral science, where, as noted above, fewer research alternatives are available.

Animal Research Committees

There is a real need for a national study on the use of animals in research. Such a study could examine current practices in animal research, examine and disseminate the latest developments in substitute methodology, acquaint the research population with alternative methods, evaluate proposals for uniform national standards and, in general, provide much needed data about the care, costs and benefits of using animals in research. Without such a factual foundation, the animal research committee, as proposed in H.R. 5725, will be repetitious, and will flood the research field with numerous potentially contradictory rulings, thereby creating increased ambiguity and reducing the number of objective criteria for decisionmaking in the research community.

The proposal to require animal research committees at research institutions in large part would legislate what is already current practice at many, if not most, institutions. The establishment of animal review committees is not a concern per se. Many research facilities already have institutional committees that are charged with monitoring the care and use of laboratory animals. However, there are several problems inherent in creating a legislative mandate for such committees. For example H.R. 5725 would create

an inflexible role for the committees, ignoring the likelihood that different research programs and facilities have differing requirements and capabilities. Further, it is likely that this provision of H.R. 5725 would increase the paperwork for research facilities and the federal agencies to which research institutions report, and could divert financial, administrative and personnel resources from supporting and conducting actual research.

With regard to the composition of the animal research committees, we believe that the required participation of community representatives and veterinarians, while well intended, could cause an undesirable shift in emphasis away from overall research concerns -- but not necessarily in the direction of animal welfare -- and could place less qualified individuals in the position of reviewing research.

Many of the conditions to be addressed by the animal studies committees -- such as assessing comfort or distress -- are behavioral in nature. For example, consider the fact that some species have different environmental needs. One type of primate may require a cage that allows vertical movement while another may require a horizontal layout. Without knowing this, animal research committee members may simply evaluate environmental conditions on quantitative bases, and in this instance would look only at the number of square or cubic feet per animal without considering the cage layout. It is difficult to imagine that inclusion of a veterinarian or lay person on an animal research committee would guarantee the committee's sensitivity to this type of requirement, which is overwhelmingly behavioral in nature.

Another consideration is whether a requirement that the committee must include individuals to represent specific aspects of animal welfare would create certain procedural problems. For example, would the number and frequency of meetings depend upon whether those persons could attend? If they were not in attendance, would action taken by the committee be legitimate? Could non-attendance at meetings be used to place the institution in a position of non-compliance with the legislation, and thus ineligible to receive federal funding? Would there be opportunities for recourse in the event that research is obstructed or rejected on the basis of actions by such persons? These questions raise serious doubts about mandating representatives on the committee.

As a minimum, the structure and effectiveness of existing animal care committees should be studied before being locked into legislation. If it is determined that specific members of the committee will be responsible for specific aspects of animal care -- such as requiring that a veterinarian be on the committee in order to ensure the clinical care of animals -- then we would strongly urge that an individual scientifically trained in animal behavior also be required so that the psychological and behavioral needs of the animals will be adequately and appropriately monitored.

Statements of Assurances

In current practice, federal research proposals are required to include a number of the justifications and assurances called for in H.R. 5725. However, this bill would also require additional items which are not necessarily relevant to scientific merit or animal welfare, but which would constitute an additional burden on applicants seeking research support.

Proposals for studies involving animals already are required by the research review system to provide detailed information about experimental procedures and to justify the selection of a particular methodology. A bibliography of relevant research, including research using alternatives, is also required.

Consultation with a doctor of veterinary medicine is not currently required and could pose a problem in two respects. Such consultation would increase the cost of submitting research proposals, particularly for smaller institutions or others that might not have routine access to veterinarians. The other issue is that an assumption is being made about the effect of including a veterinarian in research planning. Specifically, it is assumed that the presence of a veterinarian will automatically enhance or ensure animal welfare. This is not necessarily the case. Rather, this assumption raises questions about whether the training and education of veterinarians qualifies them to be involved in research planning and other activities as indicated in H.R. 5725. Again, our concern is that this sort of information be in hand before legislation such as H.R. 5725 is enacted.

In sum, the requirements for justifications and assurances for the most part do not appear to establish new practices of care and use for laboratory animals. These provisions do, however, constitute a regulatory burden for research. Further, they could be restrictive by legislating the structure of research proposals. An equally important consideration is that these provisions are not necessarily going to enhance animal welfare. Hence, we believe that neither research nor improved care and use of animals will be well served by these requirements in H.R. 5725.

Funding

A final concern is that without additional funds to implement the provisions of H.R. 5725 or other animal research legislation, the net effect of such legislation will be symbolic rather than substantive. We believe that Congress would be more willing to provide funds for animal research legislation if it is demonstrated that such legislation is based on accurate data and would establish the most appropriate mechanisms. We believe it is possible and desirable to improve animal welfare without jeopardizing progress in research, but that this balance will not occur without further study.

Restatement of Summary Points

- o We recommend to the House that, before the animal research legislation is enacted, a study be conducted, such as the one proposed in H.R. 2350, The Health Research Extension Act, to address the numerous unanswered questions that surround the use of animals in research.

- o With regard to H.R. 5725, the Improved Standards for Laboratory Animals Act, there are a number of concerns regarding the bill's impact on research in general and on behavioral research in particular. Briefly, those concerns are:
 1. Several provisions in H.R. 5725 are based on assumptions rather than facts.
 2. Alternatives to the use of animals are difficult to find in the study of behavior, so the emphasis on alternatives in H.R. 5725 may have particularly adverse consequences for behavioral research.
 3. Several provisions in H.R. 5725 pose a regulatory burden for research without assuring improvement in animal welfare.
 4. The fact that no funding is included in H.R. 5725 means that the entire financial burden would fall on researchers, and would divert resources from direct support of doing research.

Again, we appreciate the opportunity to make these comments and would be pleased to provide further information or answer any questions Members of this Subcommittee might have.

TESTIMONY
IN SUPPORT OF
H. R. 5725

presented by
THE ANIMAL PROTECTION INSTITUTE OF AMERICA

The Animal Protection Institute of America, representing over 100,000 members nationwide, supports H. R. 5725, the "Improved Standards for Laboratory Animals Act", as an important step in upgrading the treatment and care of laboratory animals under the Animal Welfare Act and providing the impetus for the careful rethinking of the current heavy dependence on animal "models" in research and testing.

H. R. 5725 firmly commits the orientation of biomedical research towards reduction and replacement of live animal research through development and use of alternative, non-animal methodologies. The research community cannot fail to heed this kind of signal from the major supporter of biomedical research, the federal government. At the very least, passage of H. R. 5725 would force many researchers to rethink their often uncritical reliance on animals.

Furthermore, the need to establish animal research committees (ARCs) at all federally-funded research facilities is effectively dealt with in H. R. 5725. The Animal Protection Institute recently provided testimony to the Public Health Service regarding its proposed policy for establishing ARCs at research institutions. Many of our concerns with that policy are adequately addressed in H. R. 5725.

Notably, H. R. 5725 requires representation, on ARCs, of "community concerns regarding the welfare of animal subjects", a key element missing

from the original Public Health Service proposal. H. R. 5725 also: (1) restricts a research facility from heavily stacking its ARC with facility staff, who obviously have vested interests in the research being conducted; and (2) requires that minority views of the committee be made part of the committee's official reports. Another important aspect of H. R. 5725 is that it provides safeguards against the potential leak of confidential information and trade secrets as a result of ARC deliberations.

In a number of important ways, H. R. 5725 directs the research community to take a fresh approach; by (1) requiring training sessions--of all personnel handling or conducting research on laboratory animals--in the humane care of research animals and the ways and means of reducing animal use in research; and (2) establishing a national information service to help inquisitive and innovative scientists looking for non-animal alternatives in biomedical research.

H. R. 5725 is a first step that takes us in the right direction--reduction, and eventual elimination, of the stress and suffering experienced by millions of animals in research and testing in laboratories throughout the country. The Animal Protection Institute urges the speedy passage of this bill, as well as strong support for the U. S. Department of Agriculture's effective implementation of its measures.

Thank you.

Statement on H.R.5725

Ann Squire, Ph.D. (Biopsychology)
Director of Research and Education; Scientific Advisor
THE AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS

Submitted to
United States House of Representatives

September, 1984

The American Society for the Prevention of Cruelty to Animals, America's first humane society, strongly urges passage of H.R.5725 to amend the Animal Welfare Act, (7 U.S.C. S2131-2156). Animals do suffer. Animals do experience pain. Scientists have established this beyond any reasonable doubt. It is of the utmost importance, therefore, that immediate action be taken to find alternatives, in addition to those already existing, to the use of animals in experimentation. H.R.5725 addresses this crucial point by requiring research facilities to provide for annual training sessions for scientists, animal technicians and other personnel involved in animal care and treatment. The sessions must include training in research and testing methods that minimize or eliminate the use of animals and, when animals are used, limit pain and distress. Also required is training on the use of the information service of the National Agricultural Library to prevent unnecessary duplication of animal experimentation. To encourage the use of alternatives to animal experimentation, H.R.5725 further requires research facilities to specify in their report to the United States Secretary of Agriculture that the principal investigator has considered al-

ternatives to any procedure likely to produce pain or distress. In addition, H.R.5725 mandates the Secretary of Agriculture to establish an information service at the National Agricultural Library, in cooperation with the National Library of Medicine, to provide information on improved methods of animal experimentation which could reduce or replace the use of animals, minimize duplication and minimize pain and distress to animals.

Research institutions must be made more accountable when using animals than is currently the case. They must provide greater scrutiny of the humaneness of experiments involving animals. H.R.5725 helps accomplish this by requiring that each research facility establish an animal research committee. This committee would include a person representing community concerns regarding the ethical treatment of animals. Each committee would be responsible for carefully inspecting its own research facility at least twice each year, and reporting to the United States Secretary of Agriculture any violations of required standards that they might uncover.

To improve research animal care further, H.R.5725 also requires that the Secretary of Agriculture promulgate standards for exercising research dogs. It also discourages the use of an animal in more than one major operative procedure from which it is allowed to recover, and specifically provides that employees of research facilities not be discriminated against (i.e., lose their jobs) for reporting to the institution's animal research

committee any violations of the Federal Animal Welfare Act and its regulations.

H.R.5725 is not an anti-science bill. Rather, its passage would assist scientists by providing for better training and easier access to resource material. By promoting the development of research alternatives, H.R.5725 would ultimately aid scientific advancement at considerably less cost and suffering. Better trained, more knowledgeable scientists, and advanced scientific techniques on alternatives to animal use make this bill pro-science as well as pro-ethics. And scientists, like all of us, need to be reminded that in their pursuit of knowledge they, too, are bound by ethical norms and constraints. For many years, Congress has been considering a multitude of bills regarding laboratory animals. Eighteen years ago a major humane achievement took place when Congress passed the Laboratory Animal Welfare Act. Oversight hearings have strengthened that act over the years, but not enough. This year, budget cuts have seriously eroded the Act's enforcement arm. H.R.5725 puts more emphasis on compliance by providing for surveillance within each research institution. With its many other strong, reasonable features, H.R.5725 deserves Congressional support. The American Society for the Prevention of Cruelty to Animals urges passage of this legislation during this Congressional session.

1055 Cathcart Way
Stanford, CA 94305

September 15, 1984

The Chairman and Members
Subcommittee on Department Operations,
Research and Foreign Agriculture
United States House of Representatives
House Office Building
Washington, DC 20515

Gentlemen:

I appreciate the opportunity to comment on aspects of Congressman Brown's laboratory animal protection bill H.R. 5725, from the viewpoint of a biomedical scientist.

I believe that animal experimentation will continue to be a regrettable necessity for the progress of medical science for the foreseeable future. But I believe that the public in general, and the majority of biomedical scientists wish to limit such experimentation whenever appropriate alternatives can be found, to apply strict humane standards and to minimize the distress of those animals that are to be used in the more severe procedures. Existing legislation is not adequate, in my view, to ensure that such standards are met. The country that leads the world in preventive and curative medicine can afford to lead also in humane treatment of its research animals.

The bill's provision for establishment of an information service at the National Agricultural Library, and for encouragement of alternatives to painful animal procedures is much needed. Often researchers simply are too busy to dig out the information on alternatives that may be buried in the literature, and will welcome the improved access to such information that the bill provides. Often, the best species for studies on human disease is *Homo sapiens*; and the past year has seen remarkable and entirely relevant medical progress in studies using human volunteers only, in particular the successful conclusion in January of the Lipid Research Clinics study on cholesterol and heart disease prevention. With adequate concern and planning, use of higher animals for painful experiments can be considerably reduced.

I highly commend the bill's provisions for instruction of animal personnel in humane practices: if not required, it may not happen, frequently because of perceived lack of time. The requirement for a community representative sensitive to the welfare of animal subjects on Animal Research Committees is entirely appropriate. The issue of animal experimentation involves very difficult philosophical and humanitarian decisions. As with so many social issues, the public should take

- 2 -

responsibility for some of these decisions, in cooperation - not confrontation - with scientists. Both sides need to learn the facts behind sometimes distressing choices. I have found little opposition among my colleagues to the "community representative" provision; some probably recall the trepidation when, some twenty years ago, lay members were first required on Institutional Human Experimentation Committees. These committees, to oversee research work on human subjects, are now accepted as the obvious, proper way to proceed. I doubt that anyone would claim that the presence of a lay member on such committees has in any way impeded medical progress. I believe many scientists would welcome increased public observation of their animal research activities. There should be nothing to hide. If animal welfare representatives are denied reasonable access to animal research activities, a growing segment of the public will suspect biomedical scientists of occult barbarism - a sad paradox, since these hardworking and dedicated people set great store by unfettered exchange of information and engrained compassion.

H.R. 5725 provides a thoughtful, workable, modern framework for humane and parsimonious use of research animals. It is a bill that the majority of the concerned public and the biomedical research community can live with. It is important to note that it is a bill that research animals will continue to die with, but with reduced stress. It is a bill with which we can all sleep better. I earnestly solicit your support of H.R.5725, and its rapid passage.

Sincerely,



Peter D. Wood, D.Sc., Ph.D.
 Professor of Medicine (Research)
 Stanford University Medical School
 Associate Director, Stanford Center
 for Research in Disease Prevention

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